The UK back pain subpopulation study: predictors of outcome in patients receiving chiropractic treatment

by

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Declaration

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

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Laura Davies

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subacute/chronic patients

Abbreviations

AECC	Anglo-European College of Chiropractic
a priori	from the former
AUC	area under curve
BBQ	Back Beliefs Questionnaire
BC	before Christ
BCA	British Chiropractic Association
BMI	body mass index
BQ	Bournemouth Questionnaire
CAM	complementary and alternative medicine
CI	confidence interval
CPR	clinical prediction rule
CNS	central nervous system
CSQ	Coping Strategies Questionnaire
e.g.	for example (*exempli gratia*)
e-mail	electronic mail
EPV	events *per* variable
et al.	and others (*et alii*)
etc.	and so forth *(et cetera)*
FABQ	Fear Avoidance Beliefs Questionnaire
GCC	General Chiropractic Council
GDP	gross domestic product
GHQ-12	General Health Questionnaire (short version)
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
i.e.	that is to say *(id est)*

LBP	low back pain
MSK	musculoskeletal
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NRS	Numerical rating scale
ODQ	Oswestry Disability Questionnaire
ÖMPSQ	Örebro Musculoskeletal Pain Screening Questionnaire
OR	odds ratio
PASS-20	Pain Anxiety Symptoms Scale (short version)
PASW	predictive analytics software
per	through, by means of
PGIC	Patient's Global Impression of Change
post hoc	after the fact (*post hoc ergo propter hoc*)
pre hoc	before the fact
PSS	Pain Self-efficacy Scale
p value	probability value
RCT	randomised controlled trial
ROC	receiver operating characteristic curve
SBT	STarT Back Screening Tool
SD	standard deviation
SIM card	subscriber identity module card
SMS	short message service
SMT	spinal manipulative therapy
SPSS	statistical package for the social sciences
UK	United Kingdom
USA	United States of America
via	by way of
vs.	against (*versus*)

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Dissemination

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Presentations

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Dedication

For Sarah and Ruth

Abstract

Introduction: Non-specific low back pain is a common condition that continues to place a considerable burden on society. Various treatment approaches have emerged which are aimed at targeting non-specific low back pain and one of the most commonly recommended of these is spinal manipulative therapy, which is a central component of the chiropractic approach. However, despite observations in clinical practice in which some individuals respond well, results from clinical trials of treatment interventions for low back pain, such as chiropractic, are repeatedly seen to have small effect sizes. A plausible explanation for this is that low back pain may be considered a heterogeneous condition consisting of a number of subgroups of patients. Previously highlighted as a research priority, these subgroups and their predictive factors for outcome are beginning to be identified among low back pain patients receiving chiropractic treatment; however they are largely unstudied in the UK chiropractic patient population. The overall aim of this prospective cohort study was to attempt to identify predictors of outcomes in the short, medium and long term in low back pain patients undergoing chiropractic treatment in primary care settings throughout the UK.

Methods: All practising members of the British Chiropractic Association were invited to participate in the study. Each chiropractor was required to recruit 10 consecutive low back pain patients. Patients were eligible for inclusion if they were between 18 and 60 years of age; presenting with a new episode of low back pain with or without leg pain; no treatment for low back pain within the previous 3 months; not pregnant; no contraindications to chiropractic care; a mobile phone user. All participating patients completed an informed consent form. Data were recorded utilising self-report paper questionnaires by patients and chiropractors at baseline; and by patients only at the 4th visit, 3 months and 6 months follow-up. In addition, outcomes in the immediate short term were recorded from patients *via* text message on a daily basis for 7 days following the 1st visit. Baseline potential predictor variables encompassed demographics, clinical characteristic, clinical examination findings, work-related factors and psychosocial factors. The primary outcome was patient self-report global improvement. Patients were subgrouped according to the duration of the current episode of low back pain into acute (less than 2 weeks) and subacute/chronic (2 weeks or greater). Multivariate logistic regression analysis was used to construct prognostic models for baseline and change score variables at each follow-up.

Results: Sixty-five chiropractors and 452 low back pain patients (222 acute; 230 subacute/chronic) participated in the study. The loss to follow-up at 6 months was approximately 65%. Almost 60% of patients participated in the text message study and the response rate was high (96%). The acute patients reported higher pain and disability at baseline; however a greater proportion of these patients were categorised as improved at each follow-up. The greatest drop in pain scores occurred in the 1st week in both

subgroups. Several baseline predictor variables were independently associated with improvement at follow-up; however these differed between the subgroups with the exception of the patient-practitioner relationship. Early changes in pain were independently associated with improvement for the acute and subacute/chronic patients in the short and medium term. The discriminative ability of the baseline and change score prognostic models varied from weak to acceptable.

Conclusion: The investigation presented here contributes to the body of research concerning prognostic factors, specifically those in the immediate short term, in the UK chiropractic LBP patient population and for being the largest study of its kind to date in the UK. Furthermore, this study highlights the potential impact of the patient-practitioner relationship on outcome in low back pain patients receiving chiropractic care. Although several baseline variables predicted improvement at follow-up, the importance of early change as a prognostic indicator is emphasised.

Chapter 1: Impact and chiropractic management of low back pain

1.1 The impact of low back pain

Low back pain (LBP) is a prevalent, costly and potentially disabling condition for which, in the majority of patients, a precise pathological cause is seldom identified [1, 2]. In the absence of specific spinal pathology, LBP of musculoskeletal origin is referred to as non-specific or simple mechanical LBP [2-4]. In order to establish the diagnosis, a process referred to as diagnostic triage is invariably performed to classify the patient in to 1 of 3 broad categories: serious spinal pathology, nerve root pain/spinal stenosis, and non-specific LBP [2, 5, 6]. The approach of diagnostic triage facilitates decision making regarding treatment and management and is recommended by national clinical guidelines as an essential part of the treatment encounter even though the level of evidence for this is not particularly strong [2, 5, 6].

Non-specific LBP is defined by the European guidelines for the management of acute LBP as "pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without leg pain" [2]. However, the broad and idiopathic nature of this group precludes any clear information as to treatment or management and as such this categorisation simply remains one based on the presenting symptom of pain and the anatomical region of origin. It is estimated that between 85% and 90% of LBP cases fall into the non-specific category [2, 5, 6, 7]. For the remainder of this thesis, non-specific low back pain will be referred to as LBP.

Further classification is often based on the duration of the condition, usually as acute, subacute and chronic LBP. Acute LBP typically refers to pain that has persisted for less than 6 weeks; sub-acute for between 6 and 12 weeks, and LBP that has lasted for 12 weeks or more is generally referred to as chronic LBP [2, 5]. Although these terms are widely used throughout the literature, there is some lack of consensus regarding the definition of acute LBP, even among different national guidelines [2, 5, 6]. Furthermore, a recent Delphi study [8] aimed at standardising definitions of LBP used in prevalence studies identified some discrepancy between the presumed definition for chronic LBP and observations in clinical practice, suggesting that the current usage of this term is

somewhat ambiguous. This may in part be due to confusion in the literature about the distinction between the recurrence of a new episode of LBP and an exacerbation of an existing chronic LBP problem. Overall, however, the definitions given above continue to be widely used and accepted [2].

Manek and MacGregor [7] define prevalence for LBP as "the proportion of the population that experiences low back pain at a given time, which can be at any specified point (point prevalence) or in a past period such as 1 month, 1 year or a lifetime". It is estimated that the lifetime prevalence of LBP in adults is approximately 80% [9, 10] and that the one-year prevalence is between 22% and 65% [9]. In the UK, the point prevalence of LBP is estimated to be 14% [11] with 5 million patients consulting their GP each year resulting in costs of £140.6 million. Furthermore, the NHS annual costs directly related to LBP (for hospital care and physiotherapy) are £662.6 million [12]. These annual costs represent almost 3% of the total health care expenditure in the UK and amount to 0.2% of gross domestic product (GDP) [11]. A similar picture emerges in other developed countries. The total expenditure attributable to LBP in the USA is estimated at $90.8 billion per annum [13], $26 billion of which pays for directly treating LBP representing 0.42% of GDP [11, 14].

The clinical course of LBP provides an immense challenge in terms of appropriate treatment options. It is estimated that only one in three cases of acute LBP fully resolve [11], although some confusion exists in the literature concerning the clinical course of LBP. It has frequently been quoted that the majority of acute LBP cases resolve within 3 months; instead, however, it appears that these patients had merely stopped consulting their GP after 3 months [3]. Recent systematic reviews of the clinical course of LBP [3, 15] concluded that although the clinical course of LBP sees rapid improvements occurring within the first 3 months, improvements thereafter are rather gradual. Consequently, some authors [16] have suggested redefining the clinical course of LBP as an essentially persistent condition, characterised by a cyclical exacerbation and remission of pain and activity limitation. Indeed, a recent study documenting the week to week variation of LBP recorded *via* text-messaging provides clear evidence of a proportion of patients whose symptoms follow this oscillating course [17]. Furthermore, at 6 months post-onset, despite treatment, 16% of LBP patients who were initially off work remain so; at

12 months 44% to78% of LBP patients experience relapses of pain and 26% to 37% relapses of work absence. Estimates suggest that 60% of these of these patients will experience on-going cycles of relapse and 10% do not resolve at all, forming the more persistent LBP cases that go on to consume the majority of resources [11].

1.2 Treatment and management of low back pain using spinal manipulative therapy

In the UK, back pain is the most commonly presenting musculoskeletal complaint in the primary care sector [18]. Although LBP in primary care may be managed by general practitioners (GPs), physiotherapists, chiropractors and osteopaths, invariably LBP patients initially consult their GP and approximately 9% of adults in the UK do so each year [19]. However, GPs receive relatively small amounts of training in the field of musculoskeletal complaints and report feeling ill equipped to manage patients with LBP [20]. Furthermore, GPs understandably view LBP as low priority compared to major chronic illnesses such as heart disease [20] and instead utilise pharmacological intervention or refer patients to musculoskeletal specialists, or manual therapists such as chiropractors and osteopaths [21]. Indeed, the numbers of LBP patients consulting chiropractors have seen an increase internationally and in the USA, LBP is the most common reason for patients consulting chiropractors and spinal manipulation delivered by chiropractors is the most popular complementary and alternative medicine (CAM) therapy for LBP [22].

Spinal manipulation has been practised for several millennia and some of the earliest documentation is believed to date back to ancient China in 206 BC [23]. In recent times, although spinal manipulative therapy (SMT) for many has become almost synonymous with chiropractic, the chiropractic profession began only relatively recently in 1895 in the USA [23]. Techniques for spinal manipulation have been modified by different professions; however, chiropractic SMT is defined as "the application of high-velocity, low-amplitude manual thrusts to the spinal joints slightly beyond the passive range of joint motion" [23]. Although there is an emphasis on spinal manipulation, chiropractic patients invariably receive a variety of treatments which may be considered a combined chiropractic approach. These interventions comprise physical therapy modalities,

rehabilitative exercise plans, advice regarding nutrition and lifestyle modifications including patient education [24].

A plethora of randomised controlled trials (RCTs) have been conducted investigating the effect of SMT on LBP; in fact more RCTs have been conducted for SMT than for any other treatment modality associated with LBP [23]. The findings of these RCTs have subsequently been summarised in several systematic reviews [25-27]. Among the higher quality systematic reviews, a Cochrane review [25] in 2004 compared the effectiveness of spinal manipulation relative to other individual therapies for acute and chronic LBP and concluded that SMT is statistically and clinically more effective than sham treatments and interventions known to cause harm or be ineffective, but there is no evidence that it is superior to other standard treatments for patients with acute or chronic LBP. Moreover, these findings were corroborated in subsequent Cochrane reviews [28, 29] in which the effects of SMT for chronic and acute LBP were examined respectively. Recommendations for further research into treatment and management for LBP consistently emerge from systematic reviews, reflecting the inconclusive results from clinical trials. As stated in the Cochrane review in 2004 "a truly effective therapy for these patients remains elusive" [25].

More specifically focussing on the combination of treatments that characterises chiropractic care (as opposed to SMT alone) for LBP, a review of 12 RCTs [30] incorporating acute, sub-acute and chronic LBP patients concluded that chiropractic care provided slight improvement in pain for acute and sub-acute patients in the short and medium term, and disability in the short term. However, any benefits are not long-lasting and the evidence remains equivocal as to whether chiropractic treatment provides a clinically meaningful difference when compared to other interventions. Furthermore, most of the studies included in this review were deemed at high risk of bias and the authors caution that no studies were located that compared chiropractic care to no treatment.

Despite the equivocal conclusions reached in the research literature regarding interventions for LBP such as SMT and combined chiropractic care, systematic reviews

go on to inform national clinical guidelines for LBP which have been compiled world-wide since 1990 by advisory groups and national health care agencies [23]. Different countries offer different recommendations in their national clinical guidelines regarding the use of SMT for LBP according to how the evidence is interpreted. For acute LBP, SMT is recommended in most countries [2, 6] whereas for chronic LBP, for which there are fewer guidelines [5], recommendations vary. In the UK, the recent National Institute for Health and Clinical Excellence (NICE) guideline (2009) recommends a course of SMT for persistent LBP that has lasted for more than 6 weeks but less than 12 months [31].

The European guidelines for the management of acute [2] and chronic [5] non-specific LBP represent some of the most recent and comprehensive evidence-based guidelines informing clinical practice. The European guidelines for chronic [5] LBP deliver a recommendation of "a short course of spinal manipulation/mobilisation as a treatment option for chronic low back pain". Due to the multidimensional nature of chronic LBP it presents more of a problem in terms of longer duration and significant disability. In view of this the overriding consensus is that no single intervention is likely to be effective in being the only solution in such cases. In the guidelines for acute LBP [2], spinal manipulation is recommended as second-line care, following advice (*i.e.* remaining physically active) and over-the-counter pain medication such as paracetamol, for acute patients who are failing to return to normal activities.

1.3 Overview of pain anatomy and physiology

The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" [32]. To further illustrate the complex nature of pain, a brief overview of the anatomy and physiology describing the ascending pain pathways, pain regulation, and the affective (limbic) areas associated with pain is presented.

Ascending pain pathways

Sensory information from both the internal and external environment is conveyed to the central nervous system (CNS) in afferent nerve fibres. The modality of pain is considered as one of the general senses and is conveyed to the CNS *via* spinal nerves (from the trunk and limbs) and the trigeminal nerve, cranial nerve V (from the head). For all the modalities of general sensation, including pain, a sequence of three neurones commences with the sensory receptor in the periphery and terminates with the perception of sensation in the cerebral cortex [33].

The first neurone (first-order neurone or primary afferent neurone) enters the spinal cord through a spinal nerve on the same side of the body as the peripheral receptor. In the head, the first-order neurone enters the brain stem through the trigeminal nerve. The cell body of the first-order neurone is located in the dorsal root ganglion of a spinal nerve (or the trigeminal ganglion) and transmits sensory information (i.e. pain during noxious stimulation) from a peripheral receptor (nociceptor) to the second-order neurone. The majority of first-order neurones terminate near their point of entry in the dorsal horn of the spinal cord. However, axons may ascend or descend over several spinal segments (in Lissauer's tract) before penetrating the grey matter of the dorsal horn. Consequently, dorsal root afferents may establish contacts over several segments of spinal grey matter [33, 34]. Areas within the grey matter horns of the spinal cord are divided in to ten zones (Rexed's laminae) according to cell architecture. These laminae are numbered sequentially from dorsal to ventral. Sharp, stabbing pain information is carried into the dorsal horn by fast, myelinated A-delta fibres. Slower, unmyelinated C fibres convey dull, nagging pain. The tip of the dorsal horn, the substantia gelatinosa, receives A-delta fibres in laminae I and V and C fibres in lamina II [34].

Within the CNS, the first-order neurone remains ipsilateral and synapses upon the second-order neurone, which has its cell body in the dorsal horn of the spinal cord or brain stem. The axons from the second-order neurones decussate (cross over to the contralateral side) *via* the ventral white commissure and ascend to the thalamus in the anterolateral white matter, forming the spinothalamic tract (pain information is

conveyed in the lateral spinothalamic tract). Spinothalamic fibres lie in a somatotropic arrangement with the sacral fibres on the outermost aspect of the tract [33, 34].

Primary afferent neurones that enter the brain stem in the trigeminal nerve terminate ipsilaterally in the trigeminal sensory nucleus (one of the cranial nerve nuclei). The second-order neurones decussate and ascend to the thalamus as the trigeminothalamic tract. Spinothalamic fibres join the lateral lemnsicus of the medulla and project to the thalamus where they terminate [35]. In the brain stem, collateral branches to the reticular formation project to the limbic system and cerebral cortex. Second-order sensory neurones of either spinal cord or brain stem origin converge upon the same region of the thalamus, the ventral posterior nucleus complex, where they synapse with the cell bodies of the third-order neurones. The ventral posteromedial nucleus receives information from the head whereas the ventral posterolateral nucleus receives information from the rest of the body [33].

The axons of the third-order neurones pass through the internal capsule and corona radiata, projecting to the somatosensory cortex in the postcentral gyrus of the parietal lobe [33]. There is a high degree of spatial segregation of neurones representing different parts of the body (somatotropic organisation) and this is most clearly seen in the cerebral cortex where the somatosensory area occupies a strip of cortex that extends from the medial aspect of the hemisphere (leg area) to the inferolateral aspect of the parietal lobe (head area) [33, 34, 36].

Pain regulation

The transmission of pain signals may be regulated both in the peripheral and central nervous systems. A relay system in the dorsal horn of the spinal cord, involving inter-neuronal connections within the substantia gelatinosa, enables the modification of pain input [36]. Afferent impulses conveyed to the dorsal horn in large diameter fibres (non-nociceptive) have an inhibitory effect on the substantia gelatinosa. Conversely, afferent impulses transmitted in smaller diameter fibres have an excitatory effect. The overall interaction determines the level of activity of second-order neurones in the

spinothalamic tract [36, 37]. This is referred to as the gate control theory of pain, as proposed by Melzac and Wall in 1965, and it explains how a stimulus that only activates non-nociceptive fibres (for example, 'rubbing it better') inhibits pain [35, 37].

Regions of the CNS may also be implicated in the suppression of pain. For example, electrical stimulation of the periaqueductal grey matter (midbrain) can inhibit pain perception [35]. This area receives information from higher structures processing emotional states and projects to the midline reticular and raphe nuclei, which in turn project to the dorsal horns. Furthermore, endogenous opiates (encephalins or endorphins) are thought to produce their anti-nociceptive action by activating these central regulating structures [36].

Affective areas associated with pain

Pain may result from noxious stimulation or negative emotional events and memories [38] and as such may be considered both a sensory and emotional experience. The emotional aspect of the pain experience, such as unpleasantness and intrusiveness, is referred to as the 'affective dimension of pain 'or affect [37]. As previously described, the awareness of pain occurs through projection from the thalamus to the cerebral cortex. Functional imaging studies have shown that several areas of the brain are involved in responding to noxious stimuli and furthermore a functional division has been identified between areas of sensory and affective responses in the brain [39]. Components of the somatosensory cortex, chiefly involved in pain localisation and intensity may be referred to as the lateral pain system. Areas of the brain directly involved in affect include the limbic system and medial thalamic nuclei [36, 38] and this division may be termed the medial pain system [38, 39].

The limbic system (involved in learning and memory and also with the processing of emotion) is a complex arrangement of fibre tracts and grey matter, located in the medial aspect of each temporal lobe and bordering the upper part of the brainstem. Due to extensive connections to the upper and higher parts of the CNS, the limbic system has the ability to integrate a wide variety of stimuli. It principally comprises the cingulate

gyrus, the amygdala, the hippocampus and the septal nuclei. A circuit between the limbic system, thalamus and hypothalamus (Papez circuit), further connects the cingulate gyrus (*via* the thalamic nuclei) with the hippocampus [36]. Spinal pathways to somatosensory areas of the thalamus and cortex also provide direct input in to the areas of the brain that are involved in affect. Moreover, *via* a cortico-limbic pathway, pain memory and context together with nociceptive information are combined in the interpretation of the pain experience [36].

Chapter 2: Subgrouping in low back pain

Despite the volume of research into the treatment and management of LBP, results are for the most part inconclusive or contradictory and often do not reflect observations in clinical practice, providing a constant source of frustration for clinicians. Furthermore, results that have emerged from RCTs for LBP treatments offered by primary care practitioners consistently show equivocal or at best small effect sizes, often with no demonstrable difference in effectiveness between different interventions [40-42]. As noted in the summarised highlights from the Ninth International Forum for Primary Care Research on Low Back Pain, given that research in this field has increased in quality and quantity over the past 20 years, prevention and treatment of LBP has shown little improvement [43].

As to why there exists this discrepancy between the experiences of practitioners and the findings from clinical trials, there are several feasible theories [44]. Potential reasons might include an overestimation of treatment effectiveness, as illustrated by consistently reported discrepancies between practitioners' reported experience of patients often dramatic improvement following treatment and results from clinical trials [45]; consequently even small differences are unlikely to be detected by the majority of clinical trials unless adequately powered to do so. Furthermore, the correct selection of patients for treatment may also be a plausible reason for this discrepancy. It may be that the treatments currently offered are in reality not particularly effective in themselves and instead there exists a more pronounced influence than initially recognised from various non-specific treatment effects, such as the interaction from the patient-practitioner relationship [46].

The natural history of LBP may also play a part according to when a patient is recruited to a trial. If the patient's LBP is severe at the onset then changes in symptoms may merely reflect the typically relapsing and remitting pattern of the natural course by reducing over the course of the trial, irrespective of any intervention. Moreover, regression toward the mean [47] may account for those patients with severe LBP at

baseline showing marked improvement whereas patients with more moderate LBP at initial presentation appearing to worsen [48]. A further potential explanation for the findings from clinical trials may be that inadequate or inappropriate outcome measures are being utilised thereby failing to accurately capture response to treatment [49].

However, one intriguing explanation that has been proposed is that clinical trials, in which group results are reported, may mask individual effects [50, 51]. For example, there may be some LBP patients who respond well to a particular intervention, several who do not and others whose LBP remains unchanged. It is arguable that an averaged effect from such a trial would result in small if not zero effect sizes. Hence, this may explain why many interventions for LBP are seen to have such small effects as LBP may be considered to be a heterogeneous condition consisting of a number of subgroups of patients distinguishable by presenting clinical characteristics and differential response to treatment [52, 53].

Subgrouping is not a novel concept in the medical literature and it has been widely depicted in clinical prediction rules (CPR). The purpose of a CPR is to combine relevant clinical information in order to enhance diagnostic or prognostic assessments and also to assist in classifying patients who are likely to respond favourably to a particular treatment [53, 54]. Several diverse examples of CPRs in the medical literature range from a guide to safe management of a suspected pulmonary embolism [55], to screening tests for depression [56, 57] and to estimating the risk of a major bleed in patients being treated with anticoagulation medication [58]. The use of CPRs is considered to be ideally suited to complex clinical scenarios, of which LBP is an example due to the heterogeneous nature of the condition [59, 60].

Investigation into potential subgroups within LBP has been identified as a research priority for almost two decades and recommendations for future studies increasingly identify the need for further classification and identification of subgroups of patients [1, 5, 23, 50]. At the inaugural International Forum for Primary Care research on Low Back Pain [61] the agenda for future research in primary care highlighted the concept of identifying subgroups of patients within LBP and the consequent tailoring of

appropriate treatment and management, as the highest priority. This was reiterated at the subsequent Forum in 1997 [62], and furthermore by the Cochrane Back Review Group [63] which likened questions pertaining appropriate treatment-matching and predictors of chronicity for LBP patients the "Holy Grail". Since this time, efforts in LBP research towards identifying these elusive subgroups have continued apace.

In addition to endorsement from the research community for pursuing investigation in to the concept of subgrouping, there is evidence to suggest that the majority of clinicians in primary care believe in subgrouping and subsequently formulate treatment and management decisions based on their perceptions of the heterogeneous nature of LBP. As reported by Kent and Keating [52], 93% of primary care practitioners surveyed from six professional disciplines would dispute that LBP is a homogeneous condition. Furthermore, more than 70% consider that they are able to distinguish subgroups within LBP and tailor treatment according to various patterns of signs and symptoms, albeit the higher proportion of these practitioners emerged from the physiotherapy profession as compared to GPs. However, a later study conducted by these authors [64] concluded that there was little consensus regarding specific signs and symptoms that defined individual subgroups across the different professions. Nevertheless, these findings would imply that primary care clinicians, especially musculoskeletal practitioners, are already utilising a system for subgrouping LBP patients in their care, further supporting the on-going need for research in this area.

A further argument that supports the notion of subgrouping is that it may not be a question of whether current treatments are appropriate, but instead a matter of identifying which treatment is most suited to the patient. Indeed, some evidence has emerged of LBP patients matched to appropriate treatments involving mechanical traction, spinal manipulation, stabilisation therapy and specific exercise [65-69]. However, a recent systematic review of the evidence comparing the efficacy of targeted as opposed to generic (non-targeted) manual therapy and/or exercise [70] cautions that although there is evidence hinting at support for the precise targeting of treatment to subgroups of LBP patients, those studies eligible for inclusion were inconsistent and patient samples were too small to provide confidence in guiding treatment recommendations in routine clinical practice. These findings reinforce and reiterate the

need for further research involving innovative trial designs to investigate whether subgrouping LBP patients leads to improved outcomes.

However, the progression of research into the existence and subsequent identification of subgroups within LBP has not been without its controversy. Recommendations for subgrouping LBP patients are absent from several recent guidelines of LBP [31, 71, 72,] albeit primarily due to the paucity of evidence derived from clinical trials. In addition, there has been notable controversy in the literature regarding the use of appropriate methodological approaches in LBP subgrouping studies [49, 70, 73].

Several approaches to subgrouping research in LBP have been proposed. These may be based on a patient's likely response to a specific treatment (treatment effect modifier subgroups); the presentation of signs and symptoms that corresponds to diagnostic subgroups; or particular prognoses, termed prognostic factor subgroups [49, 70]. In conjunction with identifying different subgroups of LBP patients, the development of CPRs in manual therapies has increasingly been reported in the literature, with particular emphasis on treatment responsiveness [66, 67, 74, 75]. For studies aiming to identify subgroups and further develop a CPR, several hierarchical stages have been described comprising three broad steps referred to as derivation, validation and impact analysis [53, 54, 76].

In derivation studies, the aim is to establish whether particular variables predict the defined outcome. The majority of CPR studies reported in the literature are derivation studies [70, 73] and it is important to note that at this stage, the CPR is not considered ready for clinical use [53]. However, it has been suggested that although not yet validated, derived CPRs may be of some clinical utility as they can allude to key predictors of outcome [77]. Once predictive factors of outcome have been identified at the derivation stage, a series of validation studies are conducted in which these factors are tested in different settings, thereby assessing internal and external validity. The final stage of impact analysis investigates whether introducing the CPR to clinical practice improves patient outcomes [53, 54].

However, subgrouping research has been shown to be strewn with potential methodological difficulties and inconsistencies [70, 78-80]. The variability in methods between studies has precluded meaningful comparisons, as illustrated by conclusions from several recent systematic reviews of CPRs in LBP [60, 81] and subgroups of LBP patients likely to respond to manual therapy [82]. Moreover, one of the most prominent areas of confusion concerning subgrouping in the literature arose from a failure to accurately differentiate treatment effect modifiers from prognostic factors [49, 70, 73]. Treatment effect modifiers concern the likely response to a particular treatment whereas prognostic factors identify patients who are likely to have different outcomes or recovery rates regardless of the treatment given [49, 70, 73.] This distinction clearly has significant implications for the choice of methods suitable for use in subgrouping research. As previously emphasised by Beattie and Nelson [54], of key importance is that the study design and methods of statistical analysis are appropriate for the aim the study.

In order to identify treatment effect modifiers, the study design must incorporate a control group or second arm at the very least. However, several studies exist in the literature reporting subgroups of LBP patients who have responded to treatment despite using longitudinal study designs more appropriate for identifying prognostic factors [67, 74, 75]. Furthermore, in prospective cohort studies investigating predictors of outcome in which all patients receive the same treatment, it is not possible to distinguish between prognostic factors and treatment effect modifiers [73]. Recently, however, several authors have sought to clarify the confusion surrounding treatment effect modifiers and prognostic factors, although this issue further emphasises the importance of methodological rigour in this potential minefield [49, 70, 73].

Despite the large volume of derivation studies in the literature of manual therapy interventions for LBP, comparatively few of these have progressed through the validation stage [49, 70, 73, 83, 84] of which the following are notable examples. A CPR involving LBP patients in primary care that has progressed substantially through the stages of development and validation is the STarT Back Screening Tool (SBT) [85, 86]. This subgrouping tool classifies LBP patients as being at low, medium or high risk for poor outcome and treatment is subsequently targeted based on potentially modifiable

risk factors for chronicity identified using a brief, user-friendly tool comprising 9 questions [85-87].

The measurement properties of the SBT [88] have been compared with and found to be similar to those of the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ), a widely used and externally validated tool used to similarly differentiate LBP patients [89]. Furthermore, a quality improvement study, the Implementation study to improve Patient Care through Targeted treatment for Back pain (IMPaCT Back study), is currently being conducted in primary care in the UK to introduce and assess the effect of the STarT Back subgrouping tool on patients, clinicians and health resources [87, 90].

A further example of a CPR for patients with LBP likely to benefit from SMT was developed and validated by Flynn *et al*. [66] and Childs *et al*. [67] respectively. The CPR comprised 5 variables including duration of symptoms for less than 16 days, internal rotation of more than 35 degrees for at least one hip, hypomobility of the lumbar spine, no symptoms distal to the knee, and a Fear Avoidance Behaviour Questionnaire (FABQ) work subscale score of less than 19. Patients who were positive on the CPR, as determined by the presence of 4 out of 5 variables, and who scored greater than a 50% improvement on Oswestry Disability Questionnaire (ODQ) scores could be identified *a priori* as likely to respond favourably to SMT.

However, despite the low numbers of patients included in the derivation and validation studies [66, 67,] this CPR has proceeded to be widely cited in the literature as evidence for the use of SMT in LBP. In 2008, Hancock *et al*. [91] performed an independent evaluation of this CPR based on secondary analysis of a RCT investigating the efficacy of SMT. The authors investigated whether or not this CPR would generalise to a different group of patients receiving SMT but concluded that the CPR performed no better than chance in identifying which patients with acute LBP would respond well to SMT. However, in the original studies [66, 67] a single, non-specific manipulation was used on all patients regardless of presentation, whereas Hancock *et al.* [91] delivered treatment tailored to each patient's unique presentation, as this was deemed to be more representative of current clinical practice.

Treatment effect modifier studies, such as the development of CPRs, provide valuable clinical information concerning a patient's likely response to a particular intervention. However, the identification of prognostic factors also has considerable clinical utility for educating patients about their likely prognosis and rate of recovery, and for informing the management of these patients [92]. For example, identifying prognostic factors that are potentially modifiable may enable the specific targeting of appropriate treatment approaches [93]. As LBP is a highly common and costly condition for which a specific cause remains unidentified and the evidence for effective treatment is not particularly strong [94], prognostic research in LBP has consequently become an area of key importance [95].

Chapter 3: Prognosis and prognostic factors in low back pain

3.1 Prognosis and prognostic factors of low back pain in primary care

Prognosis describes the likely course or predicts the outcome of a health-related complaint over a period of time [93]. Accordingly, prognostic studies attempt to answer questions broadly pertaining to the probable course, factors that are associated with the outcomes, and the identification of risk groups of patients with differing outcomes [93].

There are many prognostic studies in the LBP literature, the majority of which explore the association with poor outcome [83, 94, 95]. Of the large quantity of potential prognostic variables investigated, significant associations with poor outcome have been identified including long duration of LBP [96], poor health status [97], high levels of pain [96, 98] and psychological factors [99, 100]. Furthermore, Hayden *et al.* [95] report those that are consistent between studies are found in the domains of the LBP episode characteristics (e.g. high functional disability), individual characteristics (e.g. poor general health), psychological factors (e.g. increased stress levels), work and social environments (e.g. heavy physical work; compensation claims).

However, several contradictory findings have also been reported. For example, both employment [101, 102] and unemployment [103] have been identified as prognostic factors in LBP research. The disparity in findings has largely been attributed to methodological inconsistencies, such as varying outcome measures used and different periods of time to follow-up, as highlighted by several systematic reviews of prognostic factors in LBP [91, 104]. Indeed, in a recent systematic 'review of reviews' of LBP prognosis [95], the authors cautioned against drawing conclusions about prognostic factors in LBP due to the methodological discrepancies in both the primary and review literature.

Few studies have compared whether prognostic factors differ if patients are subgrouped according to duration of LBP episode. A recent study compared prognostic factors for disability at 12 months follow-up for acute and chronic LBP patients [105]. This study

reported that similar prognostic factors were associated with disability in the long term in both duration subgroups. Moreover, these prognostic variables were from diverse domains incorporating being unemployed, experiencing widespread pain and a high level of chronic pain and disability, and catastophising. These findings largely confirm those from the few other similar studies concluding that there is considerable overlap in prognostic factors between LBP patients subgrouped by duration [106, 107].

In addition to investigating whether there are similarities in prognostic factors between duration subgroups, the notion of there being 'generic' prognostic variables for multiple sites of musculoskeletal (MSK) pain has recently been explored [108]. Historically, prognostic studies of MSK pain in primary care have largely focussed on separate anatomical sites of pain, such as the low back or neck. However, in a recent systematic review of prospective cohort studies across different sites of MSK pain [108] the authors identified several 'generic' prognostic indicators, defined as being associated with poor outcome in at least two studies at different anatomical sites. However, they state that conclusions are limited due to differing methodological approaches and the inclusion of comparatively few prospective studies of non-spinal MSK pain in primary care.

3.2 Prognostic factors in low back pain patients receiving chiropractic care

For over a decade, several prospective studies have been conducted in chiropractic LBP patient populations in which predictors of outcome have begun to be identified. The following narrative review comprises a description of these prognostic studies with particular focus on the study design, potential predictor variables included, and outcome measures used. Furthermore, significant findings will be described together with any specific patterns identified from comparing the results between studies. Throughout this section, the studies referred to and referenced in the text are described in Table 3.1. In assessing the literature, the intention was not to employ stringent methodological criteria to construct a systematic review, but rather to attempt to provide a descriptive synthesis of the literature, presented here as a structured narrative review.

3.2.1 Description of studies and methodology

Twelve studies were identified, all of which were conducted in Europe (Table 3.1). The initial study, published in 2002 [109] was conducted in Sweden. Thereafter, six studies were conducted in Scandinavia between 2004 and 2009 under the Nordic Back Pain Subpopulation Program: four in Sweden [110-113], one in Norway [114], and one study in Finland [115]. The remaining five studies were undertaken in the UK between 2007 and 2012 [116-120].

The overall design utilised was a prospective cohort and as such, these were longitudinal studies that attempted to identify prognostic variables associated with the outcome at pre-defined follow-up points. The absence of control groups precludes any causative relationship between the amelioration of symptoms and the treatment delivered. As shown in Table 3.1, all the Scandinavian studies were conducted in multiple centres (chiropractic clinics), whereas the UK studies were either single-centre or conducted in a small group-practice arrangement. Participants (chiropractors and patients) were all recruited using convenience sampling. Furthermore, chiropractic treatment was delivered in a pragmatic manner, as decided by individual practitioners. Patients were only eligible for inclusion if they presented with LBP. Additionally, several studies permitted patients with or without radiating leg pain; one study specified that leg pain (if present) must be above the knee [116]. Without exception, those patients with any contraindications to chiropractic care were excluded from participating. Moreover, in the majority of the Scandinavian studies, previous chiropractic treatment received by patients within a specified time-frame prior to the onset of the study further warranted exclusion.

Duration categories of the LBP complaint (such as persistent, non-persistent, and acute), were also used to determine the study population (Table 3.1). In the early Swedish and Norwegian studies [109, 110, 114], persistent LBP was defined as more than 2 weeks duration at presentation combined with a total of 30 days or more of LBP in the previous 12 months (the opposite of which defined non-persistent LBP). However, in a recent UK study [119] persistent and acute LBP were defined by the current LBP episode of 7 or more weeks and less than 7 weeks respectively.

Follow-ups were conducted in the short, medium and long terms. Outcomes in the short term were invariably collected at a return visit to the chiropractic clinic, whereas in the medium and longer terms, data were obtained by postal or internet questionnaires. As shown in Table 3.1, time intervals for follow-up were typically at the 2nd visit, 4th visit, 3 months and 12 months from the initial chiropractic consultation. When comparing all the studies, the earliest initial follow-up occurred at the 2nd visit to the chiropractic clinic [109-111, 115, 118], whereas the latest final follow-up took place at 2 years [116].

3.2.2 Description of baseline and change-score potential predictor variables

The vast majority of baseline data were obtained from patient self-report questionnaires. In addition, chiropractors reported on patients' responses to several of the clinically-orientated questions and response to the initial treatment. Clinical examination findings predominantly comprised objective tests performed and documented by the chiropractors.

Potential predictor variables were derived from several domains and these are specified for each of the individual studies in Table 3.1. In summary, however, the baseline variables principally comprised: demographics (e.g. age, gender); present LBP complaint (e.g. pain severity, pain pattern, disability, current duration, associated leg pain); previous LBP (e.g. total duration during previous year; pain pattern); occupational factors (e.g. employed or not, shift worker); lifestyle and general health status (e.g. BMI, pain in other areas, smoking, alcohol consumption, medication use, frequency and intensity of physical exercise, social benefit); clinical examination findings (e.g. type of onset; objective tests e.g. lumbar ranges of motion, positive nerve root signs); patient's attitudes and expectations of recovery; chiropractors' expectations of patient's recovery; patients' immediate response to treatment at 1st visit.

Furthermore, several validated instruments were used for data collection both at baseline and follow-up. Leboeuf-Yde *et al*. [114] included the revised Oswestry Disability Questionnaire [121] and Langworthy and Breen [116] asked patients to complete Deyo's Core Set of measures [122]. The vast majority of studies also used an eleven-point

numerical rating scale for pain intensity [123, 124]. Additionally, the Bournemouth Questionnaire [125], comprising seven 11-point numerical rating scales enquiring about pain, disability and psychosocial factors, was included in several UK studies [117, 118, 119]. Field and Newell [120] also investigated the predictive utility of the STarT Back Tool [86] in chiropractic LBP patients. This tool categorises LBP patients according to their risk of poor prognosis into low, medium and high-risk groups thereby enabling the targeting of specific treatment to each of these groups of patients.

For those studies with particular emphasis on the prognostic utility of psychological factors [113, 116, 118] additional validated instruments were used including the Fear-avoidance Beliefs Questionnaire [126]; Coping Strategies Questionnaire [127]; Back Beliefs Questionnaire [128]; Pain Self-efficacy Scale [129]; 12-item version of the General Health Questionnaire [130]; Hospital Anxiety and Depression Scale [131]; and the short form version of the Pain Anxiety Symptoms Scale [132].

In addition to data collected at baseline, the predictive utility of change in LBP status between baseline and follow-up was also investigated in several studies. Axén *et al.* [109-111] investigated early change in LBP status (patient-reported pain and disability levels, and the type of reaction to the initial treatment at the 2nd visit) and whether these factors predicted outcome in the short term (4th visit). These same change variables were subsequently investigated in a Finnish study [115]. Also in Scandinavia, Leboeuf-Yde *et al*. included change in LBP status reported in the short term (4th visit) and the potential prognostic association with outcomes in the medium and longer terms in Norwegian [112] and Swedish [114] LBP patients presenting for chiropractic treatment. In the UK, Field *et al*. [118] investigated the association of early change in psychological domain scores with outcome at 1 month. Moreover, Bolton and Hurst [119] assessed the prognostic utility of change scores from the BQ and global improvement for predicting outcomes at the 4/5th and 10th visit.

3.2.3 Description of outcome variables

The primary outcome measure in the majority of studies was patient self-report global improvement (Table 3.1). Participating LBP patients in the Scandinavian studies [109-113, 115] were required to select a response at follow-up indicating their global improvement status on a 5-point Likert scale ranging from 'definitely worse' to 'definitely better'. Subsequently, this scale was dichotomised and only those patients who chose 'definitely improved' were denoted as having improved. Similarly, in all but one of the UK studies, the patient's global impression of change (PGIC) scale was used as the primary outcome measure. The PGIC comprises 7 responses ranging from 'worse or no change' to 'a great deal better, a considerable improvement that has made all the difference', thereby evaluating overall change that is meaningful to the patient [125, 133]. Furthermore, this instrument is widely used and has been assessed in a chiropractic patient population [134]. Patients are categorised as 'improved' on the dichotomised PGIC by selecting the 6^{th} or 7^{th} response; the 5^{th} response and below therefore represents 'not improved'

In addition to global improvement, several other outcome measures have been used in the studies described here. In the first Norwegian study [114] the outcome was the number of LBP-free patients, defined as a maximum Oswestry score of 15/100 together with a maximum 1/10 pain score. A subsequent Swedish study [112], reported not only on global improvement, but also on 5 other patient self-report outcomes including current severity of LBP; current impact on daily living; duration of LBP over the previous months; resistance to developing LBP; and frequency of LBP. In one of the UK studies, satisfaction with chiropractic care (a 5-point numerical rating scale) was also measured [116]. Additionally, Deyo's Core Set and the Bournemouth Questionnaire (BQ) were utilised at follow-up.

3.2.4 Significant findings

Baseline variables

Despite the inclusion of baseline predictor variables from several broad domains (such as demographics, clinical characteristics and examination findings, psychosocial factors), of those reported to be significantly associated with outcome, few were

consistent either within or between studies. In a study of Norwegian chiropractic LBP patients [114] the predictive models most accurately predicted poor outcome (i.e. not being LBP-free), the criteria for which in the short term (at the 4th visit) comprised being female, claiming social benefit, having high levels and duration of pain, and concomitant neck pain. Although the model at 3 months resembled that at the 4th visit with the exception of social benefit, at the 12-month follow-up point it differed completely consisting solely of 2 disability-related variables (severe disability in the past year, and more than 2 weeks of reduced activity in the past year). The authors propose that this divergent pattern at 12 months distinguishes the LBP 'episode' as identified by similar profiles in the short to medium terms, from the longer-term 'disease' process. Interestingly, of the 70 potential prognostic variables investigated in this study, those that were identified could all be elicited prior to the initial consultation.

Subsequently, in a prospective study conducted in Sweden [113] the prognostic model for outcome at the 4th visit comprised the baseline variables duration of LBP during the past year, fee subsidisation, and general health status. Similarly at 3 months, the prognostic model included duration of LBP in the past year, where after this model differed with 'pain in other parts of the spine in the past year'. Furthermore, in a study conducted by Bolton and Hurst in 2011 [119] of acute and persistent MSK pain patients, only one baseline variable (being employed) remained in the final predictive model for improvement at 10th visit.

Duration of the current episode of LBP has been shown to be predictive for outcome [112, 114, 117]. However, in studies that categorised patients (either *pre-* or *post-hoc*) according to the current duration of LBP (*i.e.* persistent, non-persistent, acute, or chronic LBP), as the baseline variable 'duration of the current LBP episode' was used to subgroup patients, it was consequently not included in the prediction analysis. Furthermore, of those studies that enquired about duration of LBP during the previous 12 months, this variable emerged as a consistent predictor of outcome [111-113, 115]. Moreover, in a study of Swedish chiropractic patients [112] the duration of LBP over the past year was identified as being of greater prognostic value than duration of the current episode of LBP.

Studies principally focusing on the predictive utility of psychological factors [113, 116, 117] have reported either no or weak-to-moderate associations with outcome. Leboeuf-Yde *et al.* [113] specifically investigated whether psychological factors recorded at baseline were associated with outcome (improvement) in a cohort of Swedish LBP patients receiving chiropractic care. None of the baseline psychological variables were retained in the final prognostic models at either follow-up point (4th visit and 3 months). Langworthy and Breen [116] suggested that chiropractic patients might be more psychologically 'healthy' than other LBP patients presenting for treatment in primary care. Similarly, in a recent narrative review comparing psychological instruments applied to chiropractic and non-chiropractic patient populations [135], the authors concluded that the chiropractic patients had a lesser likelihood of presenting with adverse psychological scores associated with poor prognosis.

Field and Newell [120] subsequently classified chiropractic LBP patients according to the SBT, the high-risk category of which pertains to patients with a complex psychosocial profile. Despite the development and implementation of this tool in primary care settings, the authors reported that the SBT did not appear to be useful in differentiating outcomes in chiropractic patients, regardless of low, medium or high risk subgrouping in this study. Interestingly, in an earlier study by Field *et al.* [118] documenting scores from several psychological domains before and after the initial chiropractic consultation, the authors reported a predictive model with high post-visit psychological scores (FAB, CSQ) for poor outcome at 1 month, suggesting change scores of the psychological variables are of greater predictive utility than the baseline variables measured.

When comparing the setting in which these studies were conducted, all those from Scandinavia involved multiple clinics, whereas the UK studies were conducted either by a small group of chiropractic clinics or were single-centre which may have implications for the generalisability of findings. Moreover, the sample sizes varied considerably between several studies. For example, the numbers of patients included at baseline consistently ranged between 600 and 1000 (Table 3.1) in the Scandinavian studies whereas in the other studies this varied between less than 100 [118] to over 2000 patients [119]. Indeed, in the study conducted by Field *et al.* [118], although large odds ratios were

generated in the prediction analysis (e.g. 13.5), the associated confidence intervals were very wide (2.5 to 71.4) and the authors propose that this imprecision is most likely due to the impact of a relatively small sample size (71 patients).

One of the main limitations to emerge from several of the studies was the numbers of patients who dropped-out at successive outcome measurement points. To minimise this potential issue of dropout and therefore enhance compliance of participating chiropractors and consequently the patients, the Scandinavian studies implemented a specific strategy of communication with the chiropractors that was conducted throughout the data collection period. Generally, loss to follow-up was comparatively lower in these studies, as demonstrated by the relatively high response rates at outcome measurement points (Table 3.1). Although these 'compliant' chiropractors were recruited to subsequent studies, it is not known whether these were among the most research-minded practitioners and therefore representative of the profession.

This relatively low loss to follow-up contrasts with two single-centre studies from the UK. Bolton and Hurst [119] reported that insufficient data were available for meaningful analysis of the acute patient group at the 10th visit follow-up, which consequently precluded the construction of a predictive model for this group of patients. In an earlier UK study [116] due to the high rate of attrition at the final follow-up (2 years) insufficient data were available to conduct any prediction analysis. This perhaps illustrates how longitudinal studies may be particularly prone to loss to follow-up.

Change variables

In several studies [109-111, 115, 118] outcomes were collected in the short term only. Overall, a key finding to emerge from these studies was the importance of early change in LBP status on outcomes in the short term.

The early Scandinavian studies showed that from 3 prognostic profiles constructed *a priori* based on response to the 1st treatment, type of reaction to the 1st treatment, and pain and disability status reported at the 2nd visit, it was possible to predict those patients with persistent LBP who would be 'definitely improved' at the 4th visit [109] and by the 2nd visit those non-persistent LBP patients who would not improve in the short term [110]. In a later study [112] these authors further developed 5 prognostic models *a priori* incorporating the 3 previous prognostic profiles together with additional baseline data. Of these, the most significant predictive model for poor outcome comprised a longer duration of LBP during the previous 12 months, presence of leg pain, and no definite improvement reported at the 2nd visit (Table 3.1).

The findings from the Swedish study [111] were subsequently reproduced in a study of Finnish chiropractic LBP patients [115]. However, after incorporating several additional baseline variables in the analysis (BMI, general health, pain in other parts of the spine) a similar prognostic model emerged (Table 3.1) except that body mass index (BMI) replaced longer duration of LBP over the previous 12 months. Specifically, these studies [110-112, 116], have consistently shown that data collected at baseline and in the early course predicts those patients who will or will not improve in the short term.

The first study under the Nordic Back Pain Subpopulation Program investigated predictors of outcome in persistent LBP patients receiving chiropractic care over a 12-month period in Norway [115]. A key finding to emerge from this study showed that being LBP-free at the 4th visit was strongly associated with LBP-free status at 3 and 12 months (relative risk of 3.0 and 3.1 respectively). Furthermore, a more recent prospective study of chiropractic musculoskeletal (MSK) pain patients conducted in the UK [119] reported that improvement in the short term for persistent MSK pain patients was significantly associated with improvement (odds ratio of 5.4) at the 10th visit. These authors also reported that short-term change in work FAB predicted improvement at the 10th visit in persistent MSK pain patients. Once again, these studies highlight the important impact of change experienced during the clinical course on outcome.

3.2.5 Summary and conclusion

Twelve prospective studies reported primary data on predictors of outcome in patients with LBP receiving chiropractic treatment. Although several predictor variables were identified overall, the predictive models for outcome were weak-to-moderate. Moreover, there was little consistency in the predictive models at each follow-up and when comparing studies with the exception of early change variables. Recently, the emerging predictive utility of change variables as reported by Axén *et al*. [111] and Malmqvist *et al*. [115] was further emphasised by Field *et al*. [118] From a clinical perspective, those LBP patients who do not show improvement in the early course are more likely to have a poorer prognosis both in the short and longer terms. Subsequently, Bolton and Hurst [119] concluded that early improvement and the inclusion of change variables is of key importance in future prognostic studies.

Table 3.1 Description of outcome prediction studies in low back pain patients receiving chiropractic treatment

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 109 **Axén I *et al.*** **Can patient reactions to the first chiropractic treatment predict early favourable treatment outcome in persistent low back pain?** **J Manipulative Physiol Ther. 2002; 25 (7):450-54.**	Sweden	Persistent LBP patients +/- leg pain; LBP duration of > 2 weeks at 1st visit and minimum of 30 days in total during previous 12 months; no chiropractic treatment in previous 3 months.	53 chiropractors 615 LBP patients	1) 2nd visit 2) 4th visit	Age, sex, LBP intensity (past 24 h),disability description, duration/pain pattern of current episode, duration/pain pattern during past 12 months, response/reaction to treatment. 3 hypothesised prognostic groups derived from data at baseline and 2nd visit: most, intermediate, and least favourable. (Most favourable group: immediate improvement at 1st visit; reduced pain and disability, and a common or no reaction reported at 2nd visit).	Patient self-report global improvement at 4th visit ('definitely improved' on 5-point Likert scale).	56% of patients categorised as 'definitely improved' at 4th visit of which 84% were in most favourable group compared with 63% in intermediate group and 30% in least favourable group. It is possible to predict those patients who will report 'definite improvement' in the early clinical course.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 114 **Leboeuf-Yde C *et al.*** **The Nordic Back Pain Subpopulation Program: demographic and clinical predictors for outcome in patients receiving chiropractic treatment for persistent low back pain.** **J Manipulative Physiol Ther. 2004; 27(8):493-502.**	Norway	Persistent LBP patients; LBP duration of > 2 weeks at 1st visit and minimum of 30 days in total during previous 12 months; no chiropractic treatment in previous 6 months.	115 chiropractors 875 LBP patients 799 (4th visit) 598 (3 months) 512 (12 months)	1) 4th visit 2) 3 months 3) 12 months	Domains of variables: Demographics (n = 6) Previous and present LBP (n = 22) Attitudes (n = 6) Clinical findings (n = 16)	Number of LBP free patients (1/10 maximum pain score; 15/100 maximum Oswestry score).	Prognostic models most accurately predicted negative outcome (not LBP free). Predictive profile of non-LBP free patients at 4th visit: female; social benefit; high pain levels; high pain duration; persistent neck pain) was similar at 3 months (social benefit removed). At 12 months the model differed solely comprising 2 disability-related variables (severe disability in past year; > 2 weeks reduced activity past year). None of the clinical examination findings predicted outcome. Status at 4th visit strongly predicts outcome at 3 and 12 months.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 110 **Axén I *et al.*** **The Nordic Back Pain Subpopulation Program: can patient reactions to the first chiropractic treatment predict early favourable treatment outcome in non-persistent low back pain?** **J Manipulative Physiol Ther. 2005; 28(3):153-8.**	Sweden	Non-persistent LBP patients; +/- leg pain; LBP duration of < 2 weeks at 1st visit and maximum of 30 days in total during previous 12 months; no chiropractic treatment in previous 3 months.	60 chiropractors 674 LBP patients	1) 2nd visit 2) 4th visit	Age, sex, LBP intensity (past 24 h), disability description, duration/pain pattern of current episode, duration/pain pattern during past 12 months, response/reaction to treatment. 3 hypothesised prognostic groups derived from data at baseline and 2nd visit: best, intermediate, least favourable.	Patient self-report global improvement at 4th visit ('definitely improved' on 5-point Likert scale).	79% of patients categorised as 'definitely improved' before or at 4th visit of which 91% were in best group (immediate improvement at 1st visit; reduced pain and disability (improvement), and a common or no reaction reported at 2nd visit) compared with 76% in intermediate group and 35% in least favourable group. It is possible to predict at the 2nd visit those non-specific LBP patients undergoing chiropractic care who will not improve by the 4th visit.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 111 **Axén I *et al.*** **The Nordic Back Pain Subpopulation Program: validation and improvement of a predictive model for treatment outcome in patients with low back pain receiving chiropractic treatment.** **J Manipulative Physiol Ther. 2005; 28(6):381-5.**	Sweden	LBP patients; +/- leg pain; no chiropractic treatment in previous 3 months.	58 chiropractors 1057 LBP patients	1) 2nd visit 2) 4th visit	5 prognostic models were constructed (*pre hoc*) based on: 3 hypothesised prognostic groups derived from data at baseline and 2nd visit: best, intermediate, least favourable. Age, sex, LBP intensity (past 24 h), disability description, duration/pain pattern of current episode, duration/pain pattern during past 12 months, response/reaction to treatment.	Patient self-report global improvement at 4th visit ('definitely improved' on 5-point Likert scale)	Of the 5 prognostic models, all had high specificity (accurately identifying non-improvers) but low sensitivity (poor at identifying improvers). One model was significantly better at predicting outcome (no improvement): no definite improvement by 2nd visit; presence of leg pain; 30 days or more of LBP during past 12 months. It is possible to predict short-term outcome prior to treatment onset, and by the 2nd visit at the latest in LBP patients undergoing chiropractic care.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 112 **Leboeuf-Yde C *et al.*** **The Nordic Back Pain Subpopulation Program: long-term outcome pattern in patients with low back pain treated by chiropractors in Sweden.** **J Manipulative Physiol Ther. 2005; 28(7):472-8.**	Sweden	LBP patients; +/- leg pain; no chiropractic treatment in previous 3 months.	58 chiropractors 1054 LBP patients 983 (3 months) 601 (12 months)	1) 3 months 2) 12 months	12 subgroups defined at baseline based on: duration of current episode (1-7, 8-14, > 14 days: termed baseline 1 week, baseline 2 weeks, baseline > 2 weeks); total duration over previous year (≤ 30 or > 30 days: termed non-persistent or persistent LBP); pain pattern over the previous year (termed intermittent or daily). Patient self-report outcome (improvement) at 4th visit.	Patient self-report outcomes, 6 questions (Likert scales): current severity of LBP; current effect on daily living; duration over the past months; resistance to developing LBP; frequency of LBP; global impression of change.	2 subgroups contained the greatest numbers of patients: baseline 1 week, non-persistent LBP, intermittent pain ; and baseline > 2 weeks, persistent LBP, daily pain. These represented either extreme of the 12 subgroups. At 3 months, 70% of patients were 'definitely better' compared with 47% at 12 months. Duration of LBP at 1st visit is of less prognostic value than duration of LBP over the past year. LBP status at the 4th visit predicts outcome in the long-term.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 116 **Langworthy JM, Breen AC** **Psychosocial factors and their predictive value in chiropractic patients with low back pain: a prospective inception cohort study.** **Chiropr Osteopat. 2007; 15:5.**	UK	LBP patients (new episode); leg pain, if present, must be above knee.	Single-centre chiropractic practice (number of practitioners not specified). 158 LBP patients 101 (6 weeks) 55 (2 years)	1) 6 weeks 2) 2 years	Demographic and work-related factors (7 questions); duration of current and previous episodes; aggravating factors. Deyo's core set of outcome measures: bothersomeness, interference with work, attitude to persistent pain, days of reduced activities/off work. Fear Avoidance Beliefs Questionnaire (FABQ); Back Beliefs Questionnaire (BBQ) inevitability scale; Coping Strategies Questionnaire (CSQ) anxiety and coping scales; 12-item version General Health Questionnaire (GHQ-12).	Pain impact (Deyo's core set). Satisfaction with care (5-point NRS) recorded at 6-week follow-up only. Relative risk ratios were calculated for predictors of poor outcome.	Almost 65% patients presented with moderate to high bothersomeness scores; however, psychometric scores were generally low. Co-morbidity and inevitability were significantly associated with higher work interference at 6 weeks; LBP duration > 4 weeks was significantly associated with higher bothersomeness at 6 weeks. Due to the high attrition rate at 2 years follow-up, insufficient data were available for prediction analysis.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 117 **Newell D, Field J.** **Who will get better? Predicting clinical outcomes in a chiropractic practice.** **Clinical Chiropractic. 2007; 10, 179-186.**	UK	LBP patients	Single-centre chiropractic practice (number of chiropractors not stated). 788 LBP patients 623 (4 weeks) 583 (12 weeks)	1) 4 weeks 2) 12 weeks	BQ; gender; duration of LBP (subgroups: acute < 4 weeks; acute but recurring condition < 4 weeks R; chronic > 4 weeks).	BQ; Patient's Global Impression of Change (PGIC).	All baseline BQ scores were higher in acute (< 4 weeks) patients; females had higher baseline BQ depression scores. Approximately 74% of patients were categorised as 'better' on the PGIC at both 4 and 12 weeks. A shorter duration of LBP at baseline (< 4 weeks; 'acute' group) was significantly associated with a reduced risk of poor recovery at 4 and 12 weeks. In the acute group, males with lower depression scores and females with lower social disability scores were at reduced risk of poor outcome at 4 weeks follow-up.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 115 **Malmqvist S *et al.*** **The Nordic Back Pain Subpopulation Program: predicting outcome among chiropractic patients in Finland.** **Chiropr Osteopat. 2008; 16:13.**	Finland	LBP patients (new patients); +/- leg pain.	33 chiropractors 984 LBP patients	1) 2nd visit 2) 4th visit	Age, sex, LBP intensity (past 24 h), disability description, duration/pain pattern of current episode, duration/pain pattern during past 12 months, response/reaction to treatment, number of disabilities, better at 2nd visit, BMI, general health, pain in other parts of the spine, type of treatment, duration since 1st visit.	Patient self-report global improvement at 4th visit ('definitely improved' on 5-point Likert scale).	Over 60% of patients categorised as 'definitely better' at 4th visit. The prognostic model from previous Swedish study (Axén *et al.* 2005) was reproduced in this sample (no definite improvement by 2nd visit; presence of leg pain; 30 days or more of LBP during past 12 months). After incorporating additional variables (BMI, general health, pain in other parts of the spine), the final prognostic model comprised 3 variables: BMI, leg pain, better at 2nd visit. A dose-response between these criteria and the outcome 'definitely improved' was identified. For those LBP patients who do not improve by the 2nd visit, the short-term prognosis is poor.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 113 **Leboeuf-Yde C *et al*.** **The Nordic Subpopulation Research Programme: prediction of treatment outcome in patients with low back pain treated by chiropractors – does the psychological profile matter?** **Chiropr Osteopat. 2009; 17:14.**	Sweden	LBP patients; +/- leg pain; no chiropractic treatment in previous 3 months.	55 chiropractors 731 LBP patients 626 (4th visit) 464 (3 months)	1) 4th visit 2) 3 months	Demographics and lifestyle (5) Clinical details (7) Psychological questionnaires: HADS (Hospital Anxiety and Depression Scale) and PASS-20 (Pain Anxiety Symptoms Scale). 4th visit pain intensity past 24 h, improvement at 4th visit.	Patient self-report global improvement at 4th visit and 3 months ('definitely better' on 5-point Likert scale).	The prognostic model for outcome at 4th visit comprised: fee subsidisation; duration of LBP in past year; general health. At 3 months the prognostic model comprised: duration of LBP in the past year; pain in other parts of the spine in the past year. None of the psychological variables improved or remained significant in the final prognostic models. A positive gradient was identified in relation to number of predictor variables and outcome at both follow-up points.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 118 **Field J, Newell D, McCarthy P.** **Preliminary study into the components of the fear-avoidance model of LBP: change after an initial chiropractic visit and influence on outcome.** **Chiropr Osteopat. 2010; 18:21.**	UK	LBP patients (new patients); +/- leg pain.	9 chiropractors 71 LBP patients 65 (2nd visit) 48 (1 month)	1) 2nd visit 2) 1 month	Recorded at baseline (pre-visit) and 2nd visit (post-visit): FABQ; BBQ; CSQ catastophising sub-scale; Pain Self-efficacy Scale (PSS) functional sub-scale; an 11-point pain numerical rating scale (NRS).	PGIC at 1 month.	FAB, catastophising, self-efficacy and pain scores were significantly improved post-visit. Pre- and post-visit catastrophisation scores and post-visit PSS and BBQ scores were weakly correlated with PGIC at 1 month. Prognostic model: high post-visit CSQ and FAB scores were associated with poor outcome at 1 month. Proportion of improved/not improved patients post-visit with between 0 and 4 psychological variable scores above pre-visit group median: ≥ 2 increased the risk of poor outcome at 1 month. 7% patients with ≤ 1 raised post-visit psychological variable score reported non-improvement at 1 month compared to 72% with ≥ 2 variables.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 119 **Bolton JE, Hurst HC.** **Prognostic factors for short-term improvement in acute and persistent musculoskeletal pain consulters in primary care.** **Chiropr Man Therap. 2011; 19(1):27.**	UK	Musculoskeletal pain (MSK) patients (new episode) (acute < 7 weeks; persistent ≥ 7 weeks).	Single-centre chiropractic practice (number of chiropractors not stated) 2422 MSK patients (1335 acute; 1059 persistent) 2422 (4/5th visit) (1335 acute; 1059 persistent) 353 (10th visit) (168 acute;185 persistent)	1) 4/5th visit 2) 10th visit	Age; gender; pain diagram (anterior/posterior); areas of pain; perceived cause of pain; recovery expectation; employment status; satisfaction with work; widespread pain; past similar complaint; medication use; alcohol consumption; smoker; physical activity levels; general health status; BQ baseline and change scores.	PGIC.	Predictive models for improvement at 4/5th visit were weak and had poor discriminative ability. Predictive model for improvement at 10th visit (persistent patients only) comprised: being employed; reduced work FAB at 4/5th visit; improvement at 4/5th visit. Early improvement and the inclusion of change variables in prognostic studies are important.

Table 3.1 (continued)

Study reference	Country	Study population	Sample size and response rate	Number of follow-ups/ time since baseline	Prognostic variables investigated	Outcome measures	Results
Reference: 120 **Field J, Newell D.** **Relationship between STarT Back Screening Tool and prognosis for low back pain patients receiving spinal manipulative therapy.** **Chiropr Man Therap. 2012; 20(1):17.**	UK	LBP patients	6 chiropractic clinics (number of chiropractors not stated). 404 LBP patients 235 (14 days) 131 (30 days) 150 (90 days)	1) 14 days 2) 30 days 3) 90 days	Age; gender; leg pain (above/below knee); duration of current episode; duration of pain in past year; recurrence; seen practitioner before; STarT Back Tool (SBT) (patients categorised as low, medium, or high risk of persistent LBP with disability on the SBT);BQ.	PGIC; BQ pain sub-scale and total scores.	BQ pain and total score differed significantly between SBT risk groups (higher scores in high-risk group) at baseline and 14 days, but were not significantly different at 30 and 90 days follow-up. None of the baseline SBT risk groups were significantly associated with outcome (PGIC) in the univariate analysis, nor retained in the final predictive models for outcome at any follow-up point.

3.3 Project aim and objectives

Aim

The overall aim of this research project is to conduct a multicentre prospective cohort study to identify predictors of outcomes in the short, medium and long terms in LBP patients undergoing chiropractic treatment in primary care settings in the UK.

Objectives

Phase 1: To develop the data collection instruments as informed by the research evidence

- To construct a series of questionnaires to document variables reported by the patient before treatment and at 4th visit, 3 months and 6 months following the initial treatment visit.
- To create questions to collect patient-reported outcomes relayed by text message in the immediate short term.
- To construct questionnaires to document practice details and patient clinical findings at 1st visit as reported by the chiropractor.

Phase 2: To conduct a peer review

- To acquire opinion from a panel of experienced chiropractic practitioners and researchers regarding the design and content of the data collection instruments, study documentation and the implementation of the proposed data collection process in the clinical practice setting.
- To revise the study documentation as appropriate.

Phase 3: To conduct a pilot study

- To test the feasibility of patient recruitment and implementation of the data collection process in the day-to-day clinical practice setting.
- To test the feasibility of utilising text messaging to collect patient-reported outcomes in the immediate short term.

Phase 4: To conduct a main study

- To record demographic information and details of practice patterns from the chiropractors.
- To record potential predictors of outcome from data collected at baseline, pre-treatment, days 1-7 following 1st treatment, 4th visit and 3 months from chiropractors and patients.
- To record outcomes from data collected pre-treatment, days 1-7 following 1st treatment, 4th visit, 3 months and 6 months from patients.
- To identify variables that predict outcome in low back pain patients receiving chiropractic treatment.

Chapter 4: Development of data collection instruments

4.1 Introduction

The process of developing and refining the design and content of the data collection instruments took place over a period of several months in 2008. The data collection instruments for the study consisted of patient and clinician self-reported paper questionnaires and a series of questions sent to patients *via* text-message. During the study, questionnaires were to be completed by patients at 1st visit (both baseline and pre-treatment), 4th visit, and at 3 and 6 months from the date of the 1st visit; and by the practitioner at 1st visit only. Text messaging was to be utilised to collect patient-reported outcomes in the immediate short term, i.e. daily during the first week following 1st visit.

4.2 Design and content of questionnaires

As the majority of data collection occurred in the chiropractic clinics, the paper questionnaires were designed with the aim of minimising disruption when implemented in the clinical practice setting. To facilitate completion, the majority of questions were formatted utilising tick-boxes. Snap Survey Software, version 7 (Mercator, United Kingdom) was used to construct the questionnaires.

A pragmatic approach was adopted in developing the content of the questionnaires. Standard instruments with established validity were incorporated into a bespoke data collection tool as informed by the research evidence and consultation with clinicians and researchers. The over-arching domains of predictor variables included were as follows: patient demographics, lifestyle, general health and psychosocial factors; clinical examination findings; characteristics of both the current and previous episodes of LBP; work-related factors; the patient-practitioner relationship (or therapeutic alliance); and clinician demographics and practice patterns. Variables from these domains have been found to be associated with outcomes in LBP patients in chiropractic [111-117] and other primary care settings [96-99.]

In LBP research, it has been strongly recommended to consider using measures that are valid (measure what they purport to measure), reliable (consistency when used in different settings or multiple times) and responsive (ability to detect when change has occurred) [136]. Furthermore, is has been suggested that instruments should measure appropriate domains such as pain, disability and quality of life, which are of greatest importance to the patient [136].

There are several instruments for evaluating outcomes in LBP that consist of scales for quantifying various domains associated with the LBP complaint, such as pain and disability. The 24-item Roland Morris Disability Questionnaire [137] and 10-item Oswestry Disability Index [121] are among the most common and have both been found to be valid, reliable and responsive [121]. However, LBP is seldom a unidimensional experience for patients and therefore outcome measures that more accurately reflect the multidimensional experience of LBP are necessary. An example of this is the Bournemouth Questionnaire (BQ), a short (7-item) and comprehensive instrument based on the biopsychosocial model of musculoskeletal pain. The BQ assesses pain, disability and psychological factors (anxiety, depression, fear-avoidance beliefs in relation to work, and locus of control) and has been found to be valid and reliable for use in clinical practice settings for back [125] and neck pain patients [139]. Moreover, the responsiveness to change of this instrument has been studied [134, 140]. Consequently, the BQ was found to be practical and readily incorporated into the baseline questionnaire for the purposes of this study presented here. In addition to the BQ, the patients' impression of global change (PGIC) was measured using an eight-point Likert scale ranging from "worse" to "a great deal better and a considerable improvement that has made all the difference". This self-report questionnaire is considered the 'gold standard' of clinically important change [141], measuring the degree of change (or improvement) following treatment that is meaningful to the patient [134].

The resulting paper questionnaires constructed for the study were as follows: Patient Questionnaire Visit 1, Patient-Practitioner Questionnaire Visit 1 and Chiropractor Recording Form Visit 1 to record data at baseline. Patient Questionnaire Visit 4, Patient

Questionnaire at 3 months and Patient Questionnaire at 6 months to document outcomes at the 4th visit, and 3 and 6 months respectively (Appendix 3).

4.3 Design and content of text-messaging system

Utilising text messages, outcomes were recorded in the immediate short term. It has previously been shown that early change, during the first week following the initial consultation but previously only measured at the 2nd visit, is a predictor of outcome in the short term in chiropractic LBP patients [109-111]. Moreover, daily collection of data may further enable greater resolution as to the pattern of change during the first week.

To record outcome data from patients over 7 consecutive days following the initial consultation, the use of text-messaging or short message service (SMS) as a data collection tool provided an efficient and pragmatic solution. Indeed, this innovative method of data collection is increasingly being utilised in studies of LBP patients [17,142-144]. A specific software programme SMS-Track [145] and access to a secure and encrypted database of the patients' SMS responses was supplied by New Agenda Solutions in Denmark. SMS-Track has been approved by the Danish Data Protection Agency (Datatilsynet) and the Danish Ethics Committee of Science, demonstrating that confidentiality of data is assured and that this method has received ethics approval in another European country.

It was anticipated that large numbers of text messages would be required to send a total of 16 to each participating patient; hence text-messages were purchased in bulk quantities as text message bundles. Furthermore, to enhance user-friendliness and due to financial considerations, it was essential that the content of each question did not exceed the maximum number of 160 characters equating to one text message. The cost of the text message replies (a maximum of 15) was incurred by the patient. This was stated in the Patient Information Sheet that all patients read prior to consenting to participate in the study. StealthNET Limited in the UK supplied the text message bundles and liaised on technical compatibility with New Agenda Solutions in Denmark.

As the SMS-Track system is based in Denmark, it was necessary to obtain a UK mobile phone number for the study thereby ensuring all text message costs were charged at the UK rate as opposed to an international rate. Accordingly, a UK subscriber identity module (SIM) card was acquired from the telecommunications operator Orange.

The content of the two text-message questions consisted of 1) an 11-point numerical rating scale (NRS) for the average pain intensity perceived by the patient over the past 24 h, and 2) a five-point Likert PGIC scale ranging from "much worse" to "much better". In response to the first question, patients were instructed to reply with a number between 0 and 10 corresponding to their level of pain. Responses to the second question enquiring about global improvement were answered with a number between 1 and 5. The NRS is one of the most commonly used measures of pain intensity and is reported in the literature to be valid and reliable [146, 147]. It has also been shown to be as responsive as other pain measures in a chiropractic environment [125]. However it has been argued that the NRS alone may not accurately reflect the multidimensional experience of pain [148] and therefore a measure of global improvement, the PGIC as previously described [134] comprised the second SMS question. The content of the SMS questions has been appended (Appendix 5).

During the latter phase of the development process, the data collection instruments (paper questionnaires and text-message questions) were scrutinised by a peer review and subsequently a pilot study.

Chapter 5: Peer Review Study

5.1 Introduction

Peer review may be defined as "an evaluation by experts of the quality and pertinence of research or research proposals of other experts in the same field" [149]. The underlying principle for conducting a peer review therefore is to critically appraise the proposed research [150] and as such identify both the strengths and limitations. Conducting a peer review was an essential stage in this research project in order to acquire expert opinion concerning the data collection process and instruments prior to progressing to the pilot study. Feedback from the peer reviewers was specifically sought on the feasibility of implementing the study in a day-to-day clinical practice setting and on the content and face validity [151, 152] of the study documentation and data collection instruments.

5.2 Aim and objectives

The general aim of the peer review process was to determine the feasibility of the research project. Consequently, the objectives were to elicit detailed feedback concerning the strengths and limitations of implementing the proposed data collection process within the clinical practice setting, and the design and ease of understanding of the study documentation and data collection instruments that would be utilised. A letter accompanying the study documentation pack guided the peer reviewers toward focusing their comments on the following major domains:

- The proposed process of data collection in a clinical practice setting
- The design and content of the study documentation and data collection instruments

5.3 Methods

5.3.1 Selection of sample

Potential members of the peer review panel were selected to include relevant representation from the chiropractic profession of individuals with clinical and research experience. A purposive sample of six panel members was chosen. It was anticipated that the combined members of the panel would be able to provide comprehensive feedback on key aspects of the data collection process and data collection instruments. The six members of the panel included three registered chiropractors each of whom work full-time in their own practices (Peer Reviewers 1, 2 and 3), including one practitioner with additional research knowledge (Peer Reviewer 1); two registered chiropractors with extensive research experience and who are faculty members at a chiropractic educational institution (Peer Reviewers 4 and 5); and a senior research fellow at a chiropractic research institute (Peer Reviewer 6).

5.3.2 Procedure of peer review

Prospective panel members were initially approached by letter in September 2008 for their willingness to participate. The letter stated the aims of the study and the purpose of the peer review process together with a specified time frame for accepting participation. All prospective peer reviewers responded within the ten day period specified in the letter of invitation and all agreed to take part. Subsequently, packs containing a complete set of the study documentation were sent to the reviewers within seven days (Table 5.1). The panel members were instructed to imagine that they were a chiropractor who had agreed to participate in the study, and were requested to comment on the following points outlined in the letter accompanying the study documentation:

- Would you be able to follow the instructions and collect the required data?
- Do you understand the questions in the chiropractor questionnaire and do you feel that patients will be able to understand the questions in the patient questionnaires?

- Are there any ambiguities/difficulties/concerns with any of the questions?
- Are there any other comments on any aspect of the study you feel could improve the data collection process?

Due to geographical constraints it was not feasible to conduct a group meeting with all the peer reviewers present. Therefore, the reviewers were asked to provide their comments in writing within ten days of receiving the study pack either by e-mail or by returning the annotated study documentation. Once received, the reviewers' comments were transcribed and the key issues noted (Appendix 1). Each peer reviewer was thanked in writing for their participation.

Table 5.1: Study documentation sent to Peer Reviewers

- Covering letter for peer reviewers
    - Guidance on where to place the emphasis of the review

- Covering letter for participating chiropractors
    - Outline of enclosed study documentation; instructions concerning start date for data collection

- Operations Manual
    - Detailed description of data collection process
- Flow Chart/Step-by-Step Instructions (laminated)
    - Concise version of data collection process for quick referral
- Data Collection Envelope
    - To contain individual patient's completed questionnaires

- Data Collection Forms:
    - Participant Information Sheet
    - Informed Consent Form
    - Chiropractor Recruitment Form
    - Patient Questionnaire Visit 1
    - Patient-Practitioner Questionnaire Visit 1
    - Chiropractor Recording Form Visit 1
    - Patient Questionnaire Visit 4
    - Patient Questionnaire at 3 months
    - Patient Questionnaire at 6 months

- Clinic Manager/Receptionist letter
- Clinic Manager/Receptionist Information Sheet

5.4 Results

All six members of the peer review panel returned their written comments within the specified ten-day time frame (Appendix 1). Verbal communication was also received from Peer Reviewer 6, as this panel member was based at the same institution as the author (LD). The feedback varied considerably in terms of content and depth, largely reflecting each peer reviewer's background. The full-time practitioners focussed on the logistics and practicalities of conducting the study in a chiropractic clinic whereas the researcher, and those with research experience, placed greater emphasis on the design and content of the documentation and data collection instruments.

As expected, the issues raised primarily referred to the data collection process and the data collection instruments with several key themes consistently emerging from the panel members' comments. The first matter, predominantly raised by the practitioners, was that potential patients should not be screened for eligibility on the telephone when making an appointment at the chiropractic clinic. It was felt that asking patients to divulge personal information over the telephone was not an appropriate role for reception staff. Indeed, Peer Reviewer 1 stated that "*you are talking about new patients and asking the receptionist to "sell" them the idea of a trial as well as doing their job, which can often be difficult if the patient is nervous or unsure as to whether they want to see a chiropractor. I think this - even if explained clearly from the outset - will be a major disincentive to participation……there are also ethical problems involved in a receptionist asking a patient about their main complaint (and judgementally determining what is a primary and what is a secondary complaint), enquiring about previous treatment and asking whether a patient is pregnant.*" This view was reiterated by Peer Reviewer 2 "*many patients may be reluctant to give out personal medical information to a stranger over the phone*" and Peer Reviewer 4 *"this may be a problem, why not ask at 1st visit?"*

A further recommendation for amendment to the data collection process concerned requiring that patients arrive at the clinic 15 minutes prior to their appointment time to

complete the study forms. All of the full-time practitioners (Peer Reviewers 1, 2 and 3) considered this step to be logistically unnecessary. Peer Reviewer 1 stated that "*most chiropractors ask their patients to arrive 15 minutes early to allow for time to read/see educational material and collect demographic data and change; it might be easier to simply ask patients to turn up 15-20 minutes earlier than their appointment time*" with which Peer Reviewer 2 was in agreement "*this stage is irrelevant if the clinic gets patients in early anyway to complete paperwork*."

With regards to the study documentation, comments from the majority of the peer reviewers (2, 4 and 6) concentrated on the layout and content of the Operations Manual as these reviewers considered the manual to be excessively detailed for prospective practitioners. A further key observation, regarding the paper questionnaires, was proposed by Peer Reviewer 4 who recommended utilising different coloured paper to identify the various questionnaires. The reviewer suggested that this would facilitate implementing the questionnaires in a busy practice environment and would also be useful for describing when each questionnaire should be used "*use different colours….for example in the instructions to the chiropractor…give "pink" form to the patient, you fill in the "yellow" form*". Furthermore, to assist with implementing the data collection process in clinical practices, Peer Reviewer 1 proposed devising a checklist for the practitioners to complete comprising a series of tick boxes corresponding to each completed questionnaire.

Feedback was almost entirely absent regarding the proposed use of text messaging to participating patients. Peer Reviewer 2 briefly queried the cost of the text messages and Peer Reviewer 4 suggested that all patients be asked to bring their mobile phones with them to the clinic. However, no panel member commented on the content of either of the two text message questions that participating patients would receive.

The final key point, highlighted by Peer Reviewer 5, concerned raising the profile of the main study within the chiropractic profession as this would be crucial to the study's

success by potentially boosting practitioner participation rate. Peer Reviewer 5 further posed the question "*will there be any initial letter or announcement(s) via the different associations?*" This reviewer also recommended obtaining support of the association presidents in disseminating information about the study to the chiropractic profession.

5.5 Discussion

The peer reviewers provided valuable feedback relating to several aspects of the data collection process and data collection instruments. Potential limitations were identified pertaining to the study documentation and as a result, the relevant amendments were instigated. The primary alteration to the study documentation concerned the Operations Manual. The majority of the peer reviewers had recommended simplifying the layout and revising the content thereby improving the user-friendliness of the manual. Two further suggestions, which were considered to be particularly useful for assisting with the data collection process in the clinics, proposed colour-coding the paper questionnaires and amending the design of the Data Collection Envelopes to incorporate a tick-box checklist for practitioners to indicate completed and enclosed questionnaires.

Although the use of text messaging represents an innovative method of data collection and is unique to a study of this kind in the UK, only two reviewers commented briefly on this data collection tool. This feedback related to costs of the text messages and ensuring that patients had their mobile phone with them at the 1st visit to the clinic. However, the relevant information was clearly stated in the Operations Manual and Patient Information Sheet respectively. Further information was therefore considered unnecessary.

To address the matter of publicising the main study within the chiropractic profession, a series of articles and news features were planned for association publications prior to the recruitment stage. Furthermore, a presentation would be delivered to delegates at the 2009 British Chiropractic Association (BCA) spring conference.

5.6 Conclusion

Conducting the peer review proved to be an invaluable exercise in identifying areas of strength and limitation in the data collection process, study documentation and data collection instruments. Following consideration of the panel's comments, amendments were implemented as informed by the key issues raised including a simplified Operations Manual; colour-coding the questionnaires that would be utilised in the clinics; creating a questionnaire checklist on the Data Collection Envelopes; and devising a strategy to raise the profile of the study within the chiropractic profession. However, these were all relatively minor modifications and as such a fundamental re-working of the entire study design proved unnecessary prior to instigating the pilot study.

Chapter 6: Pilot Study

6.1 Introduction

Following modifications to the proposed data collection process and instruments, as informed by the peer review study, the next phase was to instigate a pilot or feasibility study. Essentially, conducting a pilot study would enable a "trial run" on a small scale of the planned main study. Of crucial importance was that the data collection process be tested in day-to-day clinical practice settings similar to those that would be utilised for the main study, thereby enabling difficulties inherent in the data collection process to be rectified ahead of the main study.

6.2 Aim and objectives

The general aim of the pilot study was to test key aspects of the proposed study; specifically the recruitment of chiropractors and patients, and the clarity of the study documentation and data collection instruments comprising paper questionnaires and text messages (Appendix 2). The feasibility of implementing the data collection process within chiropractic clinics also required thorough testing. Therefore, the objectives of the pilot study were as follows:

- To test the feasibility of implementing the data collection process in clinical practice settings.
- To assess the rate of chiropractor and patient recruitment to the study.
- To assess the clarity and ease of use of the study documentation pack by chiropractors and clinic reception staff.
- To assess the comprehension and ease of completion of the self-report questionnaires by chiropractors and their patients.
- To assess the clarity of content of the patient text message questions.
- To test the transfer of the text-messaging data utilising SMS-Track between patients and the software supplier, New Agenda Solutions in Denmark.

6.3 Methods

6.3.1 Selection of sample

The sample for the pilot study was obtained from the BCA membership register in October 2008. In order to minimise selection bias, a random sample was acquired utilising a random number generator, the numbers of which corresponded to individual members as they appeared in the BCA register. A maximum of ten chiropractors was required to take part in the pilot study, each recruiting a maximum of ten LBP patients. Hence the names of the first ten randomly selected BCA members were invited in writing to participate in the pilot study.

A covering letter outlining the purpose of the pilot study and what it would entail was sent to the ten selected chiropractors. A deadline of five days by which the chiropractors were asked to respond if they agreed to take part was stipulated in the covering letter. Also enclosed was a Chiropractor Recruitment Form which the chiropractors were required to complete and return, thereby indicating their willingness to participate in the pilot study. This form consisted of nine brief questions pertaining to demographic information and practice patterns. By the end of the five-day period, two chiropractors had responded by returning completed recruitment forms (20% response rate).

One week later, a second sample of twenty chiropractors was selected from the BCA register, as described above. Within five days of receiving the letter and Chiropractor Recruitment Form, two out of the twenty invited in this 2nd round had agreed to take part (10% response rate). Consequently, due to the poor response rate, a 3rd round of letters and recruitment forms was sent to a further twenty randomly selected BCA members. Of these, four responded positively within five days (20% response rate). It was decided at this stage, due to time constraints, that the pilot study would proceed with the eight chiropractors recruited so far (16% overall response rate).

6.3.2 Procedure of pilot study

It was essential to commence data collection ahead of the Christmas holiday period, in order to maximise patient compliance. Consequently, the start date for data collection for each of the three rounds of chiropractors was staggered over a two-week period from mid-November to the beginning of December 2008.

After final testing of the text-messaging system using SMS-Track [136], data collection packs were dispatched several days ahead of the specified start date to allow sufficient time for the chiropractors and their clinic staff to familiarise themselves with the data collection procedure. The initial letter of invitation had stated that participating chiropractors would be contacted throughout the pilot study for feedback concerning 1) the feasibility of conducting the study in a practice setting, and 2) any changes or improvements to the questionnaires/study documentation. In addition, practitioners were provided with the author's (LD) contact details should they have any comments or questions pertaining to the study. All correspondence with the chiropractors, whether by post, e-mail or telephone was documented by the author (LD) in written logs. Once all data had been returned, each chiropractor was thanked in writing for their participation in the study.

6.4 Results

6.4.1 Pilot chiropractor and patient data

The demographic profiles and practice patterns of the chiropractors were established from information provided by the practitioners on the Chiropractor Recruitment Forms. From Table 6.1 it can be seen that the majority of the chiropractors were male and that all except one were working in a practice with other health care professionals.

Table 6.1 Baseline characteristics of Pilot Chiropractors

Pilot Chiropractor	Gender	Age (years)	Experience (years)	Weekly hours in practice	Practice working arrangement
1	Female	41	12	10-19	With other practitioners
2	Male	47	25	39+	With other practitioners
3	Male	32	6	20-39	Sole practitioner with receptionist
4	Female	27	4	20-39	With other practitioners
5	Female	46	22	20-39	With other practitioners
6	Male	38	16	39+	With other practitioners
7	Male	34	2.5	20-39	With other practitioners
8	Male	42	19	20-39	With other practitioners

Out of the eight chiropractors who initially agreed to participate in the pilot study, three (38%) collected data for the study. Subsequent to reading the Patient Information Sheet, nine patients declined to take part in the study (4 males [44%] and 5 females [56%]; mean age 56 years; age range 34 to 94 years). Two of the chiropractors recruited ten patients each (Pilot Chiropractors 3 and 5), and one recruited six patients (Pilot Chiropractor 7) to the study. Therefore, data were returned on 26 patients of which 9 (35%) were male, and 17 (65%) were female (mean age 39 years; age range 21 to 56 years). Of the twenty-six patients who agreed to participate, 25 successfully enrolled in the text-messaging study (one patient was unable to participate due to mobile phone signal reception difficulties).

6.4.2 Feedback from the chiropractors

Throughout the duration of the pilot study, the majority of communication with the chiropractors was conducted by telephone. Overall, this means of communication became problematic as several attempts were invariably required to speak to the chiropractors directly during working hours. Consequently, e-mail addresses were obtained where possible and the ensuing e-mail correspondence proved to be a more efficient means of communication.

Feedback from the chiropractors broadly fell into the two key areas that they had been directed towards in the initial letter of invitation: 1) the feasibility of conducting the study in a day-to-day clinical practice setting, and 2) changes or improvements to the questionnaires and study documentation. Feedback was exclusively received from the three practitioners who returned data.

Of the practitioners who initially agreed to take part in the pilot study but failed to return data (5 individuals) the reasons stated were as follows. Pilot Chiropractors 1 and 2 reported experiencing difficulties in their practice and personal life respectively which impeded their ability to focus fully on the study and they therefore withdrew. Pilot Chiropractor 4 reported a decline in patient numbers and that few patients met the inclusion criteria as they did not present with LBP. Pilot Chiropractor 6 withdrew shortly after the start date due to concerns over the decline in new patient numbers and that their participation in the study may further deter new patients. Despite repeated correspondence, Pilot Chiropractor 8 failed to respond to any communication regarding the study and consequently did not return any data. The reasons for this are unknown.

Feasibility of conducting the study in a clinical practice setting

Two out of the three practitioners who completed the study (Pilot Chiropractors 3 and 5) reported that the data collection process had been relatively easy to implement and

that it had caused minimal disruption to their practices. Indeed, reception staff for Pilot Chiropractor 3 had found the process to be straightforward providing patients arrived ten minutes prior to their appointment time to complete the baseline questionnaire. The matter of patients having adequate time to complete the study paperwork was reiterated by the majority of the practitioners who emphasised the importance of this step upon which the whole data collection process almost entirely relied.

Once the patient had completed the baseline questionnaire, the remainder of the data collection process was reported as straightforward to implement. Pilot Chiropractor 3 commented that the Patient-Practitioner Questionnaire, completed part-way through a patient's consultation with the chiropractor, did not cause undue disruption. Interestingly, although not found to be disruptive, Pilot Chiropractor 7 commented that the content of Patient-Practitioner Questionnaire may put doubts in the minds of new patients as to the chiropractor's competence.

All of the chiropractors in the pilot study worked in a practice environment that had reception staff (Table 6.1). As practitioners had been randomly selected, and as they were so few, each of the practice pattern permutations would not necessarily be represented in the sample. It initially appeared from the sample of these chiropractors that as all worked with reception staff, testing the data collection process in a practice without receptionist support would not be possible. The impact on the feasibility of the data collection process in such circumstances would therefore be unknown prior to the main study. However, although Pilot Chiropractor 7 stated on the Chiropractor Recruitment Form that he was working in a clinic with other practitioners and hence receptionists, it transpired that throughout the data collection process he was temporarily without reception support. Although this chiropractor succeeded in collecting data for the study, he reported that patients arriving later than requested, as already highlighted by other chiropractors, was the most disruptive aspect of the study rather than the absence of a receptionist. Therefore, albeit due to feedback from only one practitioner, it appeared that the data collection process had been possible in a practice setting without reception support.

On only one occasion did a practitioner (Pilot Chiropractor 4) initiate contact with the author (LD) prior to the data collection start date. This practitioner required clarification that existing as well as new patients were eligible for inclusion in the study. It was confirmed that existing patients could be included providing they had not received treatment within the preceding 3 months, as stated in the Operations Manual. Conversely, a practice manager (of Pilot Chiropractor 5) required clarification that new patients as well as existing patients could be eligible for the study. Again, this practice manager was directed to the relevant study documentation where the inclusion criteria were presented.

Throughout the data collection process, practitioners were periodically contacted by the author (LD) for feedback or to ascertain if any difficulties had arisen. One of the main concerns was that the rate of patient recruitment had been slower than anticipated. Historically, the Christmas and New Year period is a relatively quiet time for chiropractic practices and indeed this was found to be the case. Furthermore, there was the potential impact of an economic recession during this period, although this was not reported by all of the chiropractors in this pilot study. Consequently, although the pilot study was initially planned to run until the end of January, the duration of the study was extended until the end of March 2009.

Changes or improvements to the questionnaires and study documentation

It was evident from the completed questionnaires that the patients and chiropractors had mostly understood the content of the questions and associated instructions, indicative of acceptable face and content validity. The use of Data Collection Envelopes for containing the patient's questionnaires worked without exception. However, the Informed Consent Form had presented some difficulties and was completed incorrectly by the majority of patients. It became apparent that the form, which was divided into two sections, the first to be completed if a patient did not consent to take part and the second section if they did consent to participate, was found to be confusing as the majority of consenting patients completed both sections. It was decided that the layout

of the form would be altered to make this distinction clearer and that the option for agreeing to participate be presented first on the form.

A minor modification was also made to the Chiropractor Recruitment Form. During the pilot study it had become evident that e-mail correspondence was the preferred means of communicating with the chiropractors. Therefore, e-mail addresses would be requested on the Chiropractor Recruitment Form for the main study.

Feedback from utilising text messaging as a data collection instrument was largely positive. Nevertheless, Pilot Chiropractor 3 reported that several patients had declined to take part in the study as it would have involved replying to the text messages over the Christmas period. Pilot Chiropractor 7 reported that one patient had been unable to participate in the text-messaging study due to weak mobile phone signal reception. This practitioner further mentioned that one patient had declined to take part in the pilot study solely due to their reluctance to be contacted by text message. Throughout the duration of the pilot study, no technical difficulties were encountered in implementing the text-messaging study or with the relaying of data using SMS-Track [144] software to and from New Agenda Solutions in Denmark.

6.5 Discussion

Three out of eight chiropractors initially recruited succeeded in collecting data for the pilot study and therefore this raised serious concerns regarding practitioner recruitment and compliance. It was recognised that it would be imperative to raise the profile of the main study within the profession to maximise numbers of participants. This reinforced plans for a presentation to be delivered at the 2009 BCA spring conference and for articles and advertisements promoting the study to be placed in professional association publications in the months preceding recruitment.

The selection of participants by random sampling may have been a factor in the poor response rate in this pilot study. Although this method was chosen to reduce the potential for selection bias, it was decided that a convenience sample would be used instead for the main study to improve practitioner participation as is frequently used in such studies for this reason. Moreover, this confirmed that recruitment for the main study would for the most part take place at the 2009 BCA spring conference where Chiropractor Recruitment Forms would be available for delegates to complete.

One of the key aims of the pilot study was to test the data collection process in day-to-day clinical practices and although this was achieved by only three chiropractors, the feedback necessitated only minor modifications to both the data collection process and instruments. However, this was a small sample which may not be representative of the profession; consequently unforeseen difficulties might arise during the main study comprising a larger sample. Although the majority of the chiropractors in this study had receptionist support, one chiropractor was able to collect data without assistance from a receptionist indicating that the process was feasible in this instance, at least for this individual.

Regular communication with chiropractors had been shown to assist with compliance in this study. However various other factors, which were not specifically due to the study itself such as personal difficulties and the potential impact of an economic recession, were also implicated in practitioners withdrawing from this study. Communication with the chiropractors *via* e-mail was identified as being preferable and therefore recruitment forms for the main study were amended accordingly to obtain e-mail addresses.

The use of text messaging was an innovative data collection method that performed well in the pilot study. Although modifications were not considered necessary to the content of the text message questions, an additional “welcome” and “thank you” text message prior to the first and after the final text message respectively were planned for the main

study, thereby enhancing the overall user-friendliness of the text-messaging aspect of the study.

6.6 Conclusion

Conducting the pilot study enabled the data collection process and instruments to be tested in several clinical practice settings prior to embarking on the main study. Although this was achieved on a smaller scale than originally anticipated, only minor amendments were indicated specifically with regards to recruitment and communication with the chiropractors. Consequently, it was decided that recruitment for the main study would take place at the 2009 BCA spring conference (thereby obtaining a convenience sample). Furthermore, to improve communication with the chiropractors the Chiropractor Recruitment Form would be revised so that the e-mail addresses of participating practitioners would be obtained at the recruitment stage.

The final modification to the study documentation concerned simplifying the layout of the patient Informed Consent Form. Although the text-messaging component of the study did not require modification, it was considered helpful to include a "welcome" and "thank you" text message for participants in the main study (Appendix 5). Overall, the consolidation of knowledge from both the peer review and the pilot study proved to be of critical value in informing the main study.

Chapter 7: Main study - Methods

7.1 Introduction

Following the implementation of amendments to the study documentation, chiropractor recruitment procedure and data collection process as informed by the peer review and pilot study, the research project progressed to the final phase of conducting the main study. As this phase of data collection would be conducted on a larger scale than the pilot study, it would consequently involve participation from a greater number of chiropractors and patients than the pilot study.

7.2 Aim and objectives

For the main study, the overall aim was to conduct a prospective cohort study of LBP patients receiving chiropractic treatment in multiple primary care settings throughout the UK, and to identify predictors of outcome in the short, medium and long terms. Therefore, the objectives for the main study were as follows:

- To document practice and demographic details from participating chiropractors.
- To document potential predictors of outcome from data collected at baseline, pre-treatment, days 1-7 following 1st treatment, 4th visit and 3 months from chiropractors and LBP patients.
- To document outcomes from data collected pre-treatment, days 1-7 following 1st treatment, 4th visit, 3 months and 6 months from LBP patients undergoing chiropractic treatment.
- To identify variables that predict outcome in LBP patients receiving chiropractic care.

7.3 Recruitment of chiropractors

7.3.1 Selection of targeted study sample

All members of the BCA registered as practising in 2009 were invited to participate in the study. Accordingly, a convenience sample of volunteers was obtained from the profession.

7.3.2 Procedure of recruitment

Prior to recruitment, in order to raise the profile of the study within the chiropractic profession, an article and news item were placed in BCA publications distributed to members. Firstly, an informative article was published in the spring edition of the quarterly-published BCA Contact magazine (spring 2009, volume 23; number 1). Subsequently, a news item was placed in the monthly BCA newsletter In Touch (March 2009, number 137). The author's (LD) contact details were provided in the news item for enquiries regarding the study.

At the 2009 BCA spring conference, with the aim of recruiting participants, a presentation was delivered to delegates outlining the purpose of the study and data collection procedure. As it was anticipated that the majority of participants would be recruited at this event, each delegate received a Chiropractor Recruitment Form to complete and return following the presentation if they agreed to participate in the study. The recruitment form requested the chiropractor's contact details including name, practice address, telephone number and e-mail address. In addition, five short tick-box questions enquired about demographics and details of practice patterns (Appendix 2).

Following the BCA conference, practising chiropractors at the Anglo-European College of Chiropractic (AECC) and several chiropractic clinics in south-west England were approached with the aim of recruiting chiropractors to the study. All those willing to participate were required to complete a Chiropractor Recruitment Form. Furthermore,

chiropractors who had previously responded positively to the BCA In Touch news item received a recruitment form by post to complete and return.

Subsequently, all chiropractors who enrolled in the study received a letter reiterating the data collection procedure and stipulating the start date for patient recruitment as the 12th May 2009. Participants were advised that a study pack containing all documentation would arrive at their clinic in the week preceding the start date thereby allowing time for the chiropractors to familiarise themselves with the data collection process and, if applicable, to train staff.

7.4 Procedure of data collection

7.4.1 Study documentation

Packs containing the requisite documentation for data collection were posted to participating chiropractors' clinics. The documentation comprised an Operations Manual for the chiropractor detailing the data collection process; a laminated Flow Chart to serve as a quick reference guide; 10 Patient Information Sheets; 25 Informed Consent Forms; a Non-Participant Envelope, and 10 Data Collection Envelopes (Appendix 4) containing 1 each of the Patient Questionnaire Visit 1, Patient-Practitioner Questionnaire Visit 1, Chiropractor Recording Form Visit 1 and Patient Questionnaire Visit 4 (Appendix 3). Furthermore, the questionnaires introduced to the clinics were printed on different coloured paper specifically to aid with identification as follows: the Patient Questionnaire Visit 1 was printed on blue paper, the Patient-Practitioner Questionnaire Visit 1 on yellow, the Chiropractor Recording Form Visit 1 on green and the Patient Questionnaire Visit 4 on pink paper.

A covering letter welcoming the chiropractor to the study and reiterating the start date for data collection was enclosed in addition to a letter for the clinic manager and/or

reception staff emphasising the importance of their role in facilitating the successful completion of data collection (Appendix 4).

Each chiropractor was assigned a unique code for the purpose of identification and all allocated Data Collection Envelopes were coded accordingly. A Non-Participant Envelope, also identified with the chiropractor's code, was provided for the Informed Consent Forms of those patients who chose not to participate. In order for chiropractors to return the completed packs, a large padded packet with attached business reply service label was also enclosed. A business reply service licence had been acquired from Royal Mail so that postage costs were not incurred by the participants. The licence number was further utilised by the patients to return the postal questionnaires at 3 and 6 months from their initial consultation.

7.4.2 Data collection process

Data collection occurred in several stages: in the chiropractic clinic at 1st and 4th visit, by SMS to the patient's mobile phone for 7 days following 1st visit and by postal questionnaire sent to the patient at 3 and 6 months (Figure 7.1).

All chiropractors commenced patient recruitment on the specified start date with the exception of one individual who had enrolled several patients in the preceding week, and four chiropractors who requested to postpone their start date by a short time. Information in the Operations Manual stated that practitioners were required to recruit 10 consecutive low back pain patients. Prior to their first consultation with the chiropractor, patients were assessed for their eligibility for the study. Patients were eligible if they fulfilled the following criteria: presenting with a new episode of low back pain (between T12 and the lower gluteal folds) as the main complaint, with or without leg pain; 18-60 years of age; literate in the English language; no treatment for the current episode of low back pain within the previous 3 months; and a mobile phone user. Patients were excluded from the study if they were deemed by the chiropractor to have any contraindications to chiropractic care or were pregnant. All participating

patients received chiropractic treatment as determined by the chiropractor. An overview of the data collection process in the clinic setting is shown in Figure 7.2.

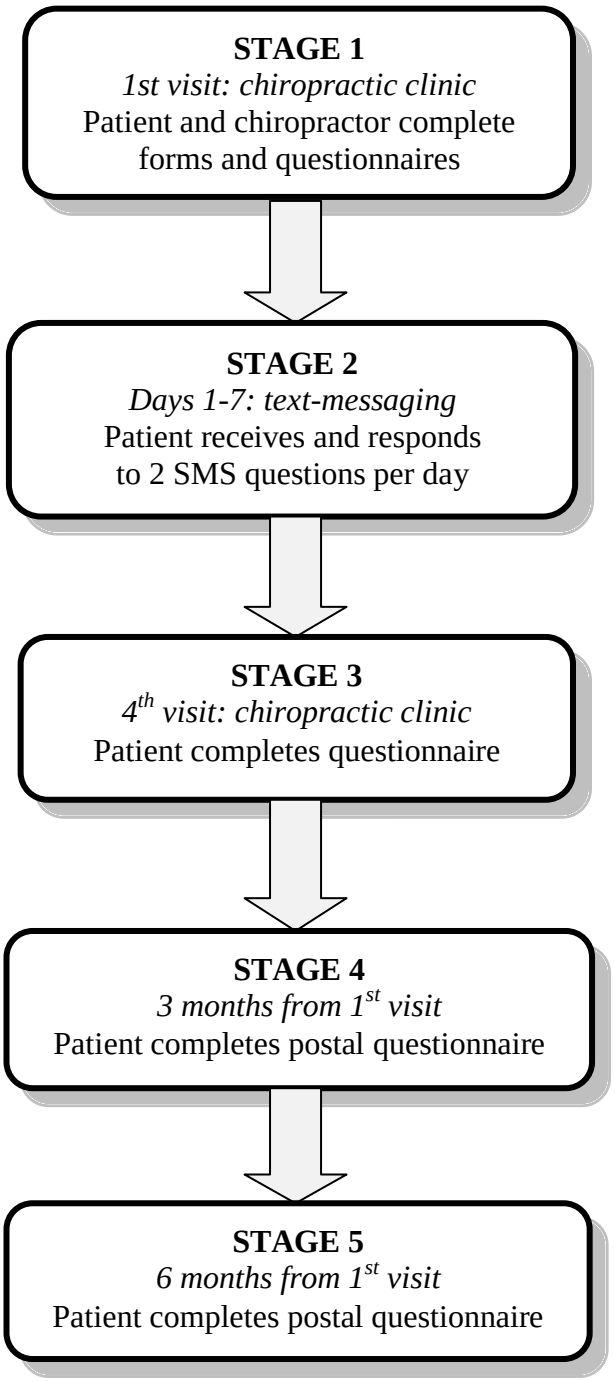


Figure 7.1 Overview of the data collection process

Potential participants were asked (by the chiropractic clinic they were attending) to arrive 10 to 15 minutes prior to their scheduled appointment time at the 1st visit to allow adequate time for a brief verbal explanation concerning the study, given by the clinic reception staff or chiropractor and, if eligible for inclusion, to read a Patient Information Sheet. Patients were permitted to ask questions if they needed to clarify their understanding of the study. If patients agreed to participate, they were required to read and complete two Informed Consent Forms; one was retained by the patient and the other remained with the patient's study documentation. Patients who declined to take part in the study were requested to indicate this in the appropriate section of the Informed Consent Form and, if they agreed, to disclose their age and gender. These consent forms were placed in the Non-Participant Envelope.

Once consent had been obtained, each participating patient was assigned a Data Collection Envelope containing the clinic-based questionnaires to be completed as instructed and then placed back in the envelope. Firstly, the baseline questionnaire (Patient Questionnaire Visit 1) was removed from the patient's Data Collection Envelope by the chiropractor or receptionist and handed to the patient to complete.

Information provided at the end of the baseline questionnaire instructed the patient to immediately send a text message ("GO") to the mobile phone number provided on the questionnaire, thereby activating their enrolment in the text-messaging study. A "welcome" text message was sent to the patient by return confirming their registration and reiterating that they would receive 2 text message questions per day for the next 7 days. Patients also recorded their mobile phone number on the baseline questionnaire so that their SMS responses and questionnaires could subsequently be united. This was the only means of identifying the patient with their SMS responses. Once completed, the baseline questionnaire was returned to the patient's Data Collection Envelope.

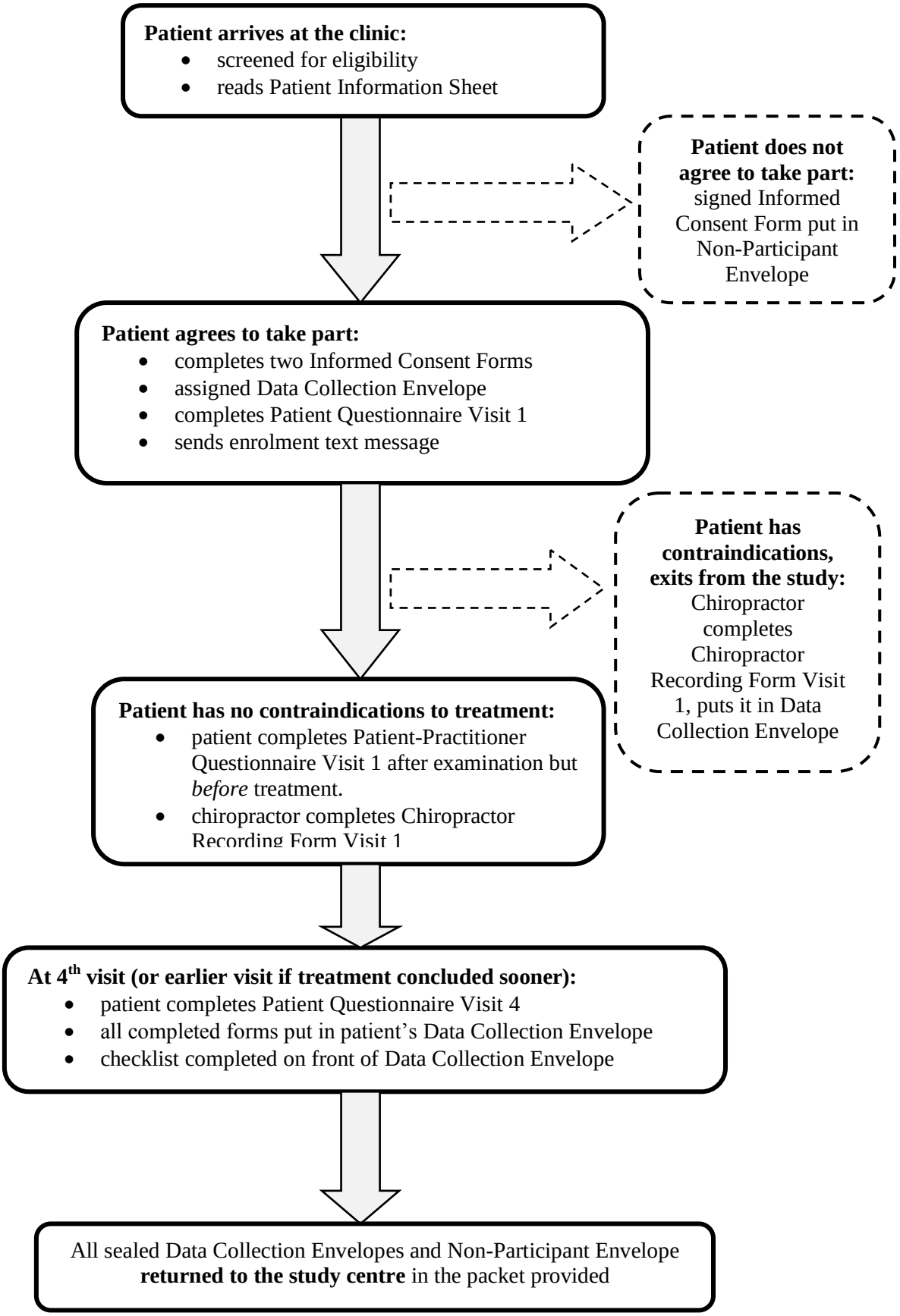


Figure 7.2 Data collection procedure in the chiropractic clinics

The next stage of data recording occurred during the patient's consultation with the chiropractor. If the patient had any contraindications to chiropractic care, the chiropractor documented this in the appropriate section on the patient's Chiropractor Recording Form Visit 1, returned the form to the individual's Data Collection Envelope and the patient exited from the study at this point. However if there were no contraindications, following the clinical examination but prior to treatment, the patient completed the Patient-Practitioner Questionnaire Visit 1 consisting of four questions with corresponding tick-boxes. As the responses to this questionnaire were to remain unseen by the practitioner, the patient was instructed to place the completed questionnaire in the accompanying self-seal envelope that was subsequently returned to the patient's Data Collection Envelope. During the consultation, the practitioner completed the Chiropractor Recording Form Visit 1 and placed this in the patient's Data Collection Envelope. This concluded data collection at the patient's 1st visit.

The collection of outcome data commenced the day following the patient's initial consultation with the chiropractor and started the day after the patient's 1st visit to the chiropractic clinic. This was entirely conducted by text-messaging whereby the patient received and responded to 2 text messages for 7 consecutive days following their enrolment in the text-messaging system at baseline. Subsequently, during the 4th visit to the chiropractic clinic (or at an earlier visit if treatment was concluded sooner), patients were required to complete the Patient Questionnaire Visit 4. If any patient failed to do so (for example, if the patient did not return for further treatment) the chiropractor was instructed to document the reason on the patient's Data Collection Envelope. Once all of the patients' data had been collected in the clinic, the chiropractor completed the checklists on the front of the Data Collection Envelopes. The sealed Data Collection Envelopes and Non-Participant Envelope were subsequently returned in the padded packet provided.

The final phase of data collection comprised two postal questionnaires. At 3 and 6 months from the date of the 1st visit, self-administered questionnaires were posted to participating patients. Enclosed with each questionnaire was a business reply service

envelope. Prior to dispatching the questionnaires, the business reply envelopes were individually coded to identify patients in case of missing name, date or illegible handwriting.

7.4.3 Processing of raw data

A database of the chiropractors' details was created containing the chiropractor's name and chiropractor code, clinic address, e-mail address, telephone number, dates that returned data were received and dates of any correspondence. The contents of the returned Data Collection Envelopes were checked to verify that all questionnaires had been completed and enclosed (and the reason provided if the Patient Questionnaire Visit 4 had not been completed). Questionnaires were also scrutinised to determine whether any patient contact details were missing prior to entering this information in to a patient database which included the patient's name, address, mobile phone number, corresponding chiropractor code and dates of 1st and 4th visit (or reason if the patient failed to attend). Relevant clinics were contacted to retrieve any missing information and, in the majority of cases, this correspondence was conducted by e-mail.

The dates that the 3 and 6 month postal questionnaires were dispatched and returned were also entered in to the patient database. Consequently, non-responders were readily identified thereby permitting follow-up procedures to be conducted. The SMS-Track program automatically entered all text-message responses with the corresponding patient's mobile phone number in to a separate database which was monitored on a regular basis.

7.4.4 Follow-up procedures with the chiropractors

Contact was maintained with the chiropractors, predominantly by e-mail, throughout the data collection period. The letter accompanying the study documentation pack had also provided contact details for any queries relating to the study. Clinics were contacted when data packs were returned to acknowledge receipt, thank the chiropractor and,

unless all 10 Data Collection Envelopes had been returned, to encourage the chiropractor's continuing effort with the study.

By the end of July 2009, as only a small number of completed Data Collection Envelopes had been returned, a letter (with a large business reply envelope enclosed) was sent to all participating chiropractors instructing them to return all completed Data Collection Envelopes from patients recruited up to 31st May 2009. Crucially, this enabled these patients to receive their 3 month postal questionnaire within the correct time frame. This process was repeated in September for all patients recruited up to 1st July 2009. Furthermore, practitioners received an e-mail reiterating this information. All e-mails requested a delivery and a read receipt to verify that practitioners had received the e-mail correspondence.

Due to the slow response rate, the end point of the study was extended by three months from August to November 2009. Moreover, in September 2009 chiropractors who had already returned data on all 10 patients were approached for a second round of data collection. The following month, all chiropractors received an e-mail together with a personal message from the next appointed president of the BCA urging and encouraging the chiropractors to return data for the study. Consequently, the study was further extended until the end of December 2009. The chiropractors were informed by e-mail of the revised end date of the study. At the end of the data collection period in the clinics, all chiropractors who had participated in the study received a letter of thanks.

7.4.5 Follow-up procedures with the patients

There was no procedure of reminders for patients who failed to respond to the daily succession of text message questions, as this was not considered feasible. Non-responders to the postal questionnaires were readily identified from the patient database for follow-up and a system of text message reminders was initially utilised for this purpose. Non-responders were contacted once. If a questionnaire had not been returned

within two weeks, a text message reminder was sent to the patient requesting that they complete and return the questionnaire they had recently received.

At 3 and 6 months following the date of the initial chiropractic consultation, participating patients received a postal questionnaire to complete and return. However, after several months of slow response, a text message alert was sent instead to patients on the day their questionnaire was dispatched. This text message primed the patient for the imminent arrival of the questionnaire and furthermore encouraged the patient's continued participation. The contents of the SMS reminders have been appended (Appendix 5).

7.5 Data Analysis

7.5.1 Preparing data for analysis

Data cleaning procedures were conducted prior to analysis. Questionnaires were excluded of patients who were not within the age range (between 18 and 60 years of age) stated in the inclusion criteria; patients with contraindications to chiropractic treatment; patients who were pregnant; and patients with missing data on the baseline questionnaire up to and including the BQ. If a patient failed to provide their mobile phone number on the baseline questionnaire and the respective chiropractic clinic was unable to retrieve this information, the patient's questionnaire data were still utilised provided that they did not warrant exclusion as previously described.

The statistical analysis software packages PASW Statistics 18 and SPSS version 17 (SPSS Inc. Chicago, Illinois 60611, USA) were used to conduct all data analysis. A coding strategy was devised prior to entering data from the questionnaires directly into SPSS. The text message data were transferred from a spread-sheet into SPSS prior to analysis. On completion of data entry, a random sample of 10% of cases was selected and checked by the author (LD) for coding anomalies. Furthermore, statistical frequency distributions were conducted to check for data entry errors.

7.5.2 Procedure of data analysis

Descriptive statistics and frequency distributions were used to describe the sample characteristics and to compute means, standard deviations, medians, ranges and percentages. Differences between duration subgroups and within group change over time were analysed using appropriate inferential tests. The majority of the categorical baseline variables were collapsed into fewer categories for ease of interpretation and clinical application. Furthermore, potential predictor variables recorded as continuous data were additionally transformed in to categorical variables at the mean or median values.

The PGIC (outcome variable), recorded at each follow-up point, was dichotomised into 'improved' and 'not improved' categories, as informed by the literature [134]. Of the 5 descriptors for the text message PGIC on Day 1 ranging from 1) 'much worse' to 5) much better, responses 1 to 4 were categorised as 'not improved' and the 5th descriptor denoted the 'improved' group. The PGIC utilised at all subsequent outcome measurement points comprised eight descriptors, the 1st to 6th of which were collapsed into a binary categorical variable 'not improved' and the 7th and 8th collapsed into the 'improved' category. Change scores (score at follow-up minus score at baseline) were calculated for the BQ total scores and each of the seven BQ sub-scales. Furthermore, as the text message pain scale utilised an eleven-point NRS, the change scores were calculated as for the BQ pain sub-scale. Change scores for SMS pain were calculated by subtracting the pain scores at each of the subsequent days (Days 2 to 7) from the pain scores on Day 1.

For the prediction analysis, logistic regression was conducted to measure the association between the predictors (independent variables) and outcome (dependent variable). Univariate logistic regression analysis was conducted for all baseline and change score predictor variables with the dichotomised PGIC outcome (improvement) at the follow-up points on Day 1, 4th visit, 3 months and 6 months. Odds ratios with 95% confidence intervals, and p-values were calculated. The alpha-level for rejecting the null hypothesis of no association was raised to 0.1 in order to avoid the exclusion of potential predictor

variables. Significant associations between predictor and change score variables and the outcome (improvement) were assessed for redundancy by correlation coefficients (0.8 or more) [153, 154].

Prior to conducting the multivariate analysis, since it was expected that some of the predictor variables significantly associated with the outcome would be strongly correlated among themselves, and including all of them in the multivariate analysis would inflate the variance of the parameter estimates, a test of multicollinearity was performed at each outcome point [155]. If multicollinearity was found to be present, the correlated variable was removed according to the strength of the association with the outcome.

Predictive models for improvement were constructed for Day 1, 4th visit, 3 months and 6 months. Separate models for baseline predictors, SMS change score and BQ change score predictor variables were constructed and subsequently combined for each outcome point. Multivariate logistic regression analysis of the significant variables ($p \leq 0.05$) was conducted to establish variables that were independently predictive of outcome. For the final models, odds ratios (with 95% confidence intervals) and p-values were calculated in addition to the sensitivity and specificity (the proportion of improved and non-improved patients correctly identified, respectively) [156]. Receiver operating characteristic (ROC) curves were constructed for each prognostic model and the ability of the model to discriminate between improved and non-improved patients was determined by area under the curve (AUC). An AUC value of 100% indicates perfect discrimination and a value of 50% indicates no discriminative ability whereas an AUC of at least 70% is considered acceptable [156].

7.6 Ethics approval

Ethics approval was granted from the Anglo-European College of Chiropractic Ethics Sub-Committee (Appendix 6).

7.7 Funding

The study was jointly funded by the British Chiropractic Association and the Anglo-European College of Chiropractic.

7.8 Conflict of interest

The author (LD) is a member of the British Chiropractic Association and an employee of the Anglo-European College of Chiropractic. However, despite funding for this study being obtained from these sources, no conditions were applied to any aspect of this research project.

Chapter 8: Main study - Results

8.1 Description of chiropractor and patient characteristics

8.1.1 Characteristics of the chiropractors

All 1,399 practising members of the BCA were invited to participate in the study. Of these, 140 chiropractors (10% of practising BCA members) were recruited to the study. The majority of the chiropractors (68%) were between 26 and 45 years of age, and 74 (53%) were male. Three quarters had been in practice for at least 20 years and 83% worked for more than 20 h *per* week, mostly in clinical practice with others (72%). It was not possible to obtain demographic data on the underlying study population of the practising BCA membership.

Of the 140 chiropractors recruited to the study, 65 (46%) succeeded in returning data. The demographics and practice pattern characteristics of the chiropractors that returned data were similar to the 75 (54%) practitioners that failed to participate in data collection. As shown in Table 8.1, approximately 50% of participant and non-participant chiropractors were male and the majority were aged between 26 and 45 years. Furthermore, approximately three-quarters of the participant and non-participant practitioners had a maximum of 20 years' experience working as a chiropractor, and almost all worked for more than 20 h *per* week and in premises with other practitioners. Chi-square analysis revealed that there were no statistically significant differences between the participant and non-participant chiropractor groups.

Table 8.1 Description of the participant (n = 65) and non-participant (n = 75) chiropractor characteristics

	Participants		Non-participants	
Variable	**Number**	**Number (%)**	**Number**	**Number (%)**
Gender	65		75	
Male		35 (54)		39 (52)
Female		30 (46)		36 (48)
Age (years)	65		74	
< 25		1 (1)		7 (10)
26-35		20 (31)		21 (28)
36-45		29 (45)		25 (34)
46-55		10 (15)		15 (20)
56-65		5 (8)		4 (5)
> 65		0 (0)		2 (3)
Years in practice	64		73	
≤ 10		29 (45)		39 (53)
11-20		21 (33)		19 (26)
21-30		12 (19)		11 (15)
31-40		2 (3)		4 (6)
Hours in practice per week	65		74	
0-9		0 (0)		2 (3)
10-19		8 (12)		14 (19)
20-39		43 (66)		42 (57)
> 39		14 (22)		16 (21)
Practice arrangement	65		75	
Sole with reception		14 (21)		13 (21)
Sole without reception		5 (8)		5 (8)
With others		44 (68)		56 (68)
Combination		2 (3)		1 (3)

8.1.2 Characteristics of the patients

As the practitioners were required to collect data from 10 consecutive LBP patients, 1,400 patients would potentially be included in the study from 140 recruited chiropractors. However, of the 65 chiropractors who succeeded in collecting data, approximately 650 patients were invited to participate in the study, of which 110 (17%) declined to take part as indicated on the returned consent forms. Of these 110 non-participants, there was an approximately even distribution between males and females (51% males). The majority (88%) of the non-participant patients were between 30 and 60 years of age with a mean and median age of 42.8 (SD 10.5) and 43 years respectively (Table 8.2).

Four hundred and eighty-three patients consented to participate in the study. The mean number of patients recruited *per* chiropractor was 7, as not all of the 65 chiropractors succeeded in returning data from 10 LBP patients. During data cleaning, 30 (6%) patients were excluded as the questionnaires were not valid. Data analysis was therefore conducted on 453 patients, 242 (53%) of which were males where the vast majority (85%) were between 30 and 60 years of age (mean age 41.2 [SD 10.0] and median age 41 years) (Table 8.2). There was no statistically significant difference in age or gender between those patients that participated and those that did not. As all participants did not always answer each question in the questionnaires, the numbers of responses varied for each question. This is noted in the respective tables.

Table 8.2 Description of participant (n = 453) and non-participant (n = 110) patient characteristics

Variable	Participants Number	Mean (SD)	Range	Median (25^{th},75^{th})	Non-participants Number	Mean (SD)	Range	Median (25^{th},75^{th})
Age (years)	453	41.2 (10)	18-60	41 (34,49)	97	42.8 (10.5)	19-60	43 (37,51)

Variable	Participants Number	Number	(%)	Non-participants Number	Number	(%)
Age (years)	453			97		
18-29		67	(15)		12	(12)
30-39		132	(29)		22	(23)
40-49		144	(32)		36	(37)
50-60		110	(24)		27	(28)
Gender	453			110		
Male		242	(53)		56	(51)
Female		211	(47)		54	(49)

8.1.2.1 Lifestyle and general health factors

The majority of the patients (88%) lived with at least one other person and were educated to college or university level (71%). Almost all reported a healthy lifestyle (84% were non-smokers and 86% took regular physical exercise one or more times *per* week) and good general health (77% reported no comorbidity), although the body mass index was categorised as overweight or obese in 62% of patients. The vast majority of patients (94%) considered their health to be similar to or better than others and that they were affected by stress only sometimes or rarely (78%). Approximately three-quarters of the patients (73%) did not have private health insurance and the vast majority had not made a claim for compensation for either this episode (94%) or a previous episode (96%) of LBP. Furthermore, almost all (99%) of the patients were not receiving incapacity benefit at the time of the first consultation (Table 8.3a).

8.1.2.2 Employment status and sick leave factors

Of the 88% of patients in paid work, 71% were employees and the majority (83%) did not work shifts. The majority of patients (84%) reported that they were either satisfied or very satisfied with their work. Approximately half (54%) were mainly seated while at work and 54% reported that their job involved frequent bending or twisting activities to their low back. Although 75% of those in paid work did not consider that their job was preventing recovery from LBP, 19% had changed to less demanding tasks at work due to LBP. Forty-six percent and 52% of patients reported that their employer and colleagues were supportive in the work place respectively. The greater proportion of those in paid work (74%) had not taken sick leave for the current episode of LBP. Furthermore, approximately half of those in paid work (56%) had not taken sick leave for a previous episode of LBP. These results are shown in Table 8.3b.

8.1.2.3 Current and previous episodes of low back pain

There was an approximately even distribution between the LBP duration categories, which ranged from a few days to more than 3 months duration, and the majority of patients (87%) reported their LBP to be moderately or extremely troublesome (Table 8.3c). Approximately two-thirds (62%) related their LBP to movement or position and 39% experienced the worst pain after sitting for more than half an hour. The majority (70%) experienced difficulty when moving from sitting to standing. Of those patients who also reported pain in specific areas other than their low back, 45% reported leg pain which in most cases (80%) was intermittent. Approximately 50% of patients stated that they had experienced their first episode of LBP during the previous 10 years and of these more than half of the patients (53%) reported that they had experienced altogether 30 days or less of intermittent LBP during the previous 12 months. For 12% of patients this was their first episode of LBP. A quarter of the patients had previously received treatment from the chiropractor they were presently consulting, and 96% of patients expected either a partial or full recovery from their current episode of LBP.

The BQ sub-scale and total scores at baseline are presented in Table 8.3d. Of the mean values for the 7 sub-scales, pain was the highest (6.0 [SD 2.1]) after which followed disability in activities of daily living, disability in social activities, work-fear avoidance beliefs, and locus of control. The sub-scales of anxiety and depression had the lowest mean scores at baseline (4.8 [SD 2.7] and 3.2 [SD 2.8] respectively). The mean value for the total BQ score at baseline was 35.0 [SD 14.4].

8.1.2.4 Clinical examination findings by the chiropractors

Following the clinical examination, the chiropractors reported that 51% of the patients experienced a sudden onset of the current episode of LBP and in 48% of cases this was induced by effort or trauma (Table 8.4). The LBP was localised to one side of the lumbar spine in approximately 50% of the patients and in the majority of cases (79%) pain could be elicited on palpation of the lumbar spine. Less than half (37%) of the patients experienced a painful catch in their low back during lumbar ranges of motion, although the range of motion that principally provoked the LBP was extension (63%).

Of those with leg pain as documented by the chiropractor (37%), positive nerve root signs were present in 34% of cases. Repeated lumbar flexion and extension tests were conducted in approximately 40% of patients with leg pain and the flexion and extension tests were found to be provocative for leg pain in 11% and 5% of cases respectively. The majority of patients (67%) reported that their LBP did not linger following the physical examination and in 66% of cases the patient reported an immediate improvement in their LBP after the treatment. Furthermore, the chiropractors expected that almost two-thirds of the patients (63%) would be fully recovered within the following 3 months.

Concerning the patients' physical constitution and mental resilience as scored by the chiropractors (0 represented 'very fragile'; 10 represented 'very robust'), the mean values for the patients' physical constitution and mental resilience were 7.3 and 7.5

respectively (Table 8.4). Additionally, as shown in Table 8.5, the mean value was less than 2 for each question pertaining to the patient-practitioner relationship as scored by the patients (0 represented ‘strongly agree’; 7 represented ‘strongly disagree’).

Table 8.3a Description of baseline patient characteristics (demographics, life style, general health, private health insurance, compensation claim and incapacity benefit) (n = 453)

Variable	Number of patients	Number	Percentage
Age (years)	453		
18-29		67	15
30-39		132	29
40-49		144	32
50-60		110	24
Gender	453		
Male		242	53
Female		211	47
Live alone	448		
Yes		56	12
No		392	88
Highest level of education	450		
Secondary school		130	29
College/university		320	71
Regular smoker	451		
Non-smoker		377	84
Yes < 20/day		65	14
Yes > 20/day		9	2
Physically active	448		
Most of the time		320	71
Some of the time		111	25
Almost never		17	4
Physical exercise *per* week	452		
None		62	14
Once or twice		183	40
Three or more times		207	46
Comorbidity	451		
Yes		103	23
No		348	77
Health comparison	451		
Much better		61	13
Better		138	30
About the same		229	51
Worse		21	5
Much worse		2	< 1
BMI classification	434		
Underweight		1	<1
Normal weight		166	38
Overweight		185	43
Obese		82	19

Table 8.3a (continued)

Variable	Number of patients	Number	Percentage
Stress effect	443		
Constant		26	6
Most of the time		73	15
Some of the time		244	55
Rarely		100	23
Private health insurance	448		
Yes, partial		42	9
Yes, full		41	9
No		325	73
Not sure		40	9
Compensation claim for current LBP episode	443		
Yes		26	6
No		417	94
Previous claim for compensation	386		
Yes		16	4
No		370	96
Claiming incapacity benefit	445		
Yes		2	< 1
No		443	> 99

Table 8.3b Description of employment status and sick leave of participating patients (n = 453)

Variable	Number of patients	Number	Percentage
In paid work	449		
Employee		317	71
Self-employed		77	17
No		53	12
Shift work	391		
Yes		68	17
No		323	83
Main type of work	380		
Heavy manual		53	14
Light manual		58	15
Walking/standing		64	17
Sitting		205	54
Frequent work activities (more than one answer possible)	396		
Bending/twisting		214	54
Driving vehicle		107	27
Lifting/carrying		120	30
Of those in pain work, job satisfaction	394		
Very satisfied		170	43
Satisfied		163	41
Neither		44	11
Dissatisfied		14	4
Very dissatisfied		3	< 1
Of those in paid work, current sick leave for LBP	394		
No		292	74
1-2 days		56	14
3-7 days		26	7
1-3 weeks		12	3
3-6 weeks		5	< 2
6 weeks-3 months		3	< 1
Sick leave for previous episode(s) of LBP	395		
Once for a few days		81	20
Once for more than a few days		46	12
Several times		46	12
No		222	56
Less demanding work tasks	388		
Yes		75	19
No		313	81

Table 8.3b (continued)

Variable	Number of patients	Number	Percentage
Employer(s) supportive	392		
Yes		179	46
No		20	5
Not relevant		193	49
Colleague(s) supportive	388		
Yes		201	52
No		15	4
Not relevant		172	44
Work preventing recovery	386		
Yes		97	25
no		289	75

Table 8.3c Description of the current episode and previous episode(s) of low back pain of participating patients (n = 453)

Variable	Number of patients	Number	Percentage
Duration	452		
1-2 days		59	13
3-7 days		98	22
1-2 weeks		66	14
2-6 weeks		81	18
6 weeks-3 months		72	16
> 3 months		76	17
Troublesome	448		
Extremely		205	45
Moderately		187	42
Slightly		55	12
Not at all		1	< 1
Description of pain pattern	441		
Comes and goes		42	10
Movement/position		273	62
Constant		126	28
Worst pain	427		
Sitting more than half an hour		168	39
Morning		110	26
Midday		32	7
Evening		49	12
Night		17	4
Multiple answers		51	12
Activities affected (more than one answer possible)	453		
Turning in bed		267	59
Sleeping		177	39
Shoes/socks		251	55
Walking		162	36
Sit to stand		319	70
Pain in other areas (more than one answer possible)	453		
Neck		135	30
Head		18	4
Shoulder(s)/arm(s)		120	26
Leg(s) above the knee		110	24
Leg(s) below the knee		94	21
Of those with leg pain	201		
Constant		41	20
Intermittent		160	80

Table 8.3c (continued)

Variable	Number of patients	Number	Percentage
Treated by this chiropractor before	451		
Yes		115	25
No		336	75
Recovery expectation for current episode	440		
Full		282	64
Partial		143	32
Probably not		13	3
Definitely not		2	<1
First ever LBP episode	450		
Never before		53	12
Within the past year		42	9
1-5 years ago		121	27
5-10 years ago		84	19
> 10 years ago		139	31
Cannot remember		11	2
LBP over the past 12 months	389		
≤ 30 days intermittent		204	53
≤ 30 days constant		25	6
> 30 days intermittent		114	29
> 30 days constant		46	12

Table 8.3d Description of the Bournemouth Questionnaire (BQ) sub-scale and total scores at baseline in participating low back pain patients (n = 453)

BQ scores	Number of patients	Mean (SD)	Median (25^{th}, 75^{th})
Pain	452	6.0 (2.1)	6.0 (5.0, 8.0)
Disability in activities of daily living	452	5.5 (2.8)	6.0 (3.0, 8.0)
Disability in social activities	450	5.1 (3.0)	5.0 (3.0, 8.0)
Anxiety	450	4.8 (2.7)	5.0 (2.0, 7.0)
Depression	451	3.2 (2.8)	3.0 (1.0, 5.0)
Work fear-avoidance beliefs	451	5.1 (3.0)	5.0 (3.0, 8.0)
Locus of control	449	5.0 (2.5)	5.0 (3.0, 7.0)
Total score	444	35.0 (14.4)	36.0 (24.0, 46.0)

Table 8.4 Description of clinical examination findings of participating patients (n = 453)

Variable	Number of patients	Number	Percentage
Type of onset	446		
Sudden		229	51
Gradual		217	49
Mode of onset	438		
Trauma		51	12
Effort		158	36
Insidious		204	46
Other		25	6
LBP localised to one side	442		
Yes		225	58
No		187	42
Pain in lumbar range of motion (more than one answer possible)	426		
Flexion		236	55
Extension		267	63
Lateral flexion		244	57
Rotation		158	37
Test not done		12	3
Painful catch during movement	438		
Yes		164	37
No		270	62
Test not done		4	<1
Pain on palpation	437		
Yes		347	79
No		90	21
Test not done		0	0
Leg pain	447		
Yes		166	37
No		281	63
Of those with leg pain, positive nerve root signs	170		
Yes		58	34
No		98	58
Possibly		12	7
Test not done		2	1
Of those with leg pain, pain with repeated flexion	172		
Yes		19	11
No		51	30
Test not done		102	59

Table 8.4 (continued)

Variable	Number of patients	Number	Percentage
Of those with leg pain, pain with repeated extension	172		
Yes		9	5
No		55	32
Test not done		108	63
Pain lingers after physical examination	437		
Yes		142	33
No		295	67
Immediate improvement following treatment	423		
Yes		279	66
No		138	33
Not treated today		6	1
Recovery expectation at 3 months by chiropractor	441		
Fully recovered		280	63
Partially recovered		131	30
Not sure		30	7

Variable	Number of patients	Mean (SD)	Median (25^{th}, 75^{th})
Chiropractor's rating of patient's physical constitution (0 – 10)	442	7.3 (1.8)	8 (6, 9)
Chiropractor's rating of patient's mental/emotional resilience (0 – 10)	442	7.5 (1.8)	8 (7, 9)

0 = very fragile; 10 = very robust

Table 8.5 Description of the patient-practitioner relationship in participating patients (n = 453)

Variable	Number of patients	Mean (SD)	Median (25^{th}, 75^{th})
Enough time with the chiropractor (0 – 7)	447	1.5 (2.4)	0 (0, 2)
The chiropractor understands and can help me (0 – 7)	448	0.9 (2.1)	0 (0, 0.8)
Agreed lifestyle changes (0 – 7)	409	0.9 (2.0)	0 (0, 1)
Shared understanding of treatment goals (0 – 7)	425	1.0 (2.1)	0 (0, 1)

0 = strongly agree; 7 = strongly disagree

8.1.3 Categorisation and analysis of acute and subacute/chronic patients

Following the descriptive analysis of the whole cohort of LBP patients, univariate logistic regression analysis was conducted for all baseline potential predictors of improvement at each outcome measurement point (Day 1, 4th visit, 3 months and 6 months). The variable pertaining to duration of the current episode of LBP was found to be significantly associated with improvement at each follow-up point, as presented in Table 8.6. Initially, the whole cohort was divided into 3 duration categories that comprised an acute group (less than 2 weeks duration, n = 222), a subacute group (between 2 and 6 weeks duration, n = 81) and a chronic group (greater than 6 weeks, n = 149). Of the entire cohort of 453 patients, one patient did not answer the question regarding duration of episode on the baseline questionnaire (Table 8.3c); hence the total number of patients in the combined subgroups was 452.

Table 8.6 Univariate logistic regression analyses of initial and collapsed categories for duration of current LBP episode in participating patients (n = 452)

Outcome measurement point (PGIC)	Initial 3 categories for duration of current LBP episode	OR (95% CI)	Collapsed 2 categories for duration of current LBP episode	OR (95% CI)
Day 1	Chronic	1	Subacute/chronic	1
	Subacute	3.4 (0.7-17.5)	Acute	2.4 (0.9-6.6)
	Acute	6.1 (1.3-28.1)		
4th visit	Chronic	1	Subacute/chronic	1
	Subacute	1.9 (1.1-3.4)	Acute	2.9 (1.7-4.8)
	Acute	3.9 (2.0-7.3)		
3 months	Chronic	1	Subacute/chronic	1
	Subacute	6.5 (2.6-16.6)	Acute	3.3 (1.6-7.0)
	Acute	5.1 (2.1 -12.1)		
6 months	Chronic	1	Subacute/chronic	1
	Subacute	2.6 (1.0-6.9)	Acute	2.9 (1.2-6.8)
	Acute	3.9 (1.3-10.8)		

OR = odds ratio; CI = confidence interval

Descriptive analysis and univariate logistic regression analysis was performed again for the three patient subgroups. As considerable similarities between the subacute and chronic groups were evident, these duration categories were combined to form a subacute/chronic group of patients (n = 230) with 2 or more weeks' duration of LBP

(Table 8.6). Of the 222 acute LBP patients, the mean age was 41.3 (SD 9.8) and the median age was 41 years while patients in the subacute/chronic group had a mean and median age of 41.0 (SD 10.1) and 41.5 years respectively. There was an approximately even distribution between males and females with 57% of males classified as acute and 50% as subacute/chronic (Table 8.7a).

Chi-square analysis and independent samples t-tests were performed for all categorical and continuous baseline variables between the acute and subacute/chronic LBP subgroups. Statistically significant differences are indicated in the respective tables (8.7a to 8.9).

Acute patient versus subacute/chronic patient characteristics

For the majority of baseline variables there was little or no statistically significant difference between the acute and subacute/chronic patients. However, there was a highly significant difference ($p < 0.001$) between the subgroups for a small number of variables relating to clinical characteristics reported by the patient, physical examination findings, and patient and practitioner expectation of recovery.

A greater proportion of the acute patients experienced difficulty with activities such as turning in bed, putting on shoes or socks, and moving from sitting to standing, compared to the subacute/chronic patients at baseline. Nevertheless, a higher percentage of the acute subgroup reported that they had experienced LBP for no more than 30 days during the previous 12 months, and comparatively fewer acute patients reported experiencing shoulder or arm pain in addition to LBP. Furthermore, the majority of acute compared to the subacute/chronic patients expected to make a full recovery from the current episode of LBP (Table 8.7c). For the BQ scores at baseline (Table 8.8), the acute cohort reported significantly higher mean values compared to the subacute/chronic group for the total score and for the domains of pain and disability in daily and social activities.

A higher proportion of acute patients reported a sudden onset of their LBP, and moreover, attributed the onset to exertion. Examination of the lumbar ranges of motion showed that the acute subgroup experienced significantly more LBP in forward flexion than the subacute/chronic cohort. However as anticipated, the chiropractors expected a higher proportion of patients with an acute episode of LBP to make a full recovery within 3 months compared to the subacute/chronic cohort (Table 8.9).

Table 8.7a Description of baseline patient characteristics (demographics, life style, general health, private health insurance, compensation claim and incapacity benefit) in acute (n = 222) and subacute/chronic (n = 230) low back pain patients

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
Age (years)	222	230		
18-29			30 (14)	37 (16)
30-39			67 (30)	65 (28)
40-49			70 (31)	73 (32)
50-60			55 (25)	55 (24)
Gender	222	230		
Male			126 (57)	115 (50)
Female			96 (43)	115 (50)
Live alone	220	227		
Yes			22 (10)	34 (15)
No			198 (90)	193 (85)
Highest level of education	222	227		
Secondary school			64 (29)	65 (29)
College/university			158 (71)	162 (71)
Regular smoker	221	229		
Non-smoker			186 (84)	190 (83)
Yes < 20/day			31 (14)	34 (15)
Yes > 20/day			4 (2)	5 (2)
Physically active*	220	227		
Most of the time			164 (74)	155 (68)
Some of the time			52 (24)	59 (26)
Almost never			4 (2)	13 (6)
Physical exercise *per* week	222	229		
None			28 (13)	34 (15)
Once or twice			85 (38)	98 (43)
Three or more times			109 (49)	97 (42)
Comorbidity*	221	229		
Yes			43 (20)	60 (26)
No			178 (80)	169 (74)
Health comparison*	221	229		
Much better			26 (12)	34 (15)
Better			72 (33)	66 (29)
About the same			118 (53)	111 (48)
Worse			5 (2)	16 (7)
Much worse			0	2 (1)

Table 8.7a (continued)

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
BMI classification	213	220		
Underweight			1 (< 1)	0
Normal weight			78 (37)	88 (40)
Overweight			96 (45)	89 (40)
Obese			38 (18)	43 (20)
Stress effect**	217	225		
Constant			11 (5)	15 (7)
Most of the time			26 (12)	47 (21)
Some of the time			124 (57)	120 (53)
Rarely			56 (26)	43 (19)
Private health insurance	221	226		
Yes, partial			15 (7)	27 (12)
Yes, full			19 (9)	22 (10)
No			166 (75)	158 (70)
Not sure			21 (9)	19 (8)
Compensation claim for current LBP episode	216	226		
Yes			9 (4)	17 (8)
No			207 (96)	209 (92)
Previous claim for compensation*	34	197		
Yes			4 (12)	12 (6)
No			30 (88)	185 (94)
Claiming incapacity benefit	219	225		
Yes			1 (< 1)	1 (< 1)
No			218 (99)	224 (99)

* $p < 0.1$; ** $p < 0.05$; *** $p < 0.001$ (Chi-square test)

Table 8.7b Description of employment status and sick leave of participating acute (n = 222) and subacute/chronic (n = 230) low back pain patients

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
In paid work*	220	228		
Employee			151 (69)	167 (73)
Self-employed			46 (21)	31 (14)
No			23 (10)	30 (13)
Shift work	195	195		
Yes			66 (33)	54 (28)
No			133 (67)	142 (72)
Main type of work	189	190		
Heavy manual			30 (16)	23 (12)
Light manual			34 (18)	24 (13)
Walking/standing			26 (14)	38 (20)
Sitting			99 (52)	105 (55)
Frequent bending or twisting at work	199	196		
No			88 (44)	93 (47)
Yes			111 (56)	103 (53)
Frequent driving of vehicle at work	199	196		
No			142 (71)	147 (75)
Yes			57 (29)	49 (25)
Frequent lifting or carrying at work	199	196		
No			142 (71)	147 (75)
Yes			57 (29)	49 (25)
Of those in pain work, job satisfaction**	198	195		
Very satisfied			95 (48)	74 (38)
Satisfied			67 (34)	96 (49)
Neither			27 (14)	17 (11)
Dissatisfied			8 (4)	6 (2)
Very dissatisfied			1 (< 1)	2 (< 1)
Of those in paid work, current sick leave for LBP**	197	196		
No			135 (69)	156 (80)
1-2 days			38 (19)	18 (9)
3-7 days			18 (9)	8 (4)
1-3 weeks			5 (3)	7 (3)
3-6 weeks			1 (< 1)	4 (2)
6 weeks-3 months			0	4 (2)

Table 8.7b (continued)

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
Sick leave for previous episode(s) of LBP	194	200		
Once for a few days			43 (22)	38 (19)
Once for more than a few days			24 (12)	22 (11)
Several times			23 (12)	23 (11)
No			104 (54)	117 (59)
Less demanding work tasks	194	193		
Yes			41 (21)	34 (18)
No			153 (79)	159 (82)
Employer(s) supportive**	198	193		
Yes			102 (51)	77 (40)
No			13 (7)	7 (4)
Not relevant			83 (42)	109 (56)
Colleague(s) supportive**	197	190		
Yes			116 (59)	85 (45)
No			7 (4)	8 (4)
Not relevant			74 (37)	97 (51)
Work preventing recovery*	193	192		
Yes			41 (21)	56 (29)
No			152 (79)	136 (71)

* $p < 0.1$; ** $p < 0.05$; *** $p < 0.001$ (Chi-square test)

Table 8.7c Description of the current episode and previous episode(s) of participating acute (n = 222) and subacute/chronic (n = 230) low back pain patients

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
Troublesome	221	226		
Extremely			111 (50)	93 (41)
Moderately			88 (40)	100 (44)
Slightly			21 (10)	33 (15)
Not at all			1 (< 1)	0
Description of pain pattern*	218	223		
Comes and goes			13 (6)	29 (13)
Movement/position			141 (65)	132 (58)
Constant			64 (29)	62 (29)
Worst pain**	214	213		
Sitting more than half an hour			98 (46)	70 (33)
Morning			57 (26)	53 (25)
Midday			17 (8)	15 (7)
Evening			15 (7)	34 (26)
Night			4 (2)	13 (6)
Multiple answers			23 (110)	28 (13)
Difficulty turning in bed**	222	230		
No			73 (33)	112 (49)
Yes			149 (67)	118 (51)
Difficulty sleeping	222	230		
No			143 (64)	132 (57)
Yes			79 (36)	98 (43)
Difficulty putting on socks/shoes**	222	230		
No			69 (31)	132 (57)
Yes			153 (69)	98 (43)
Difficulty going for a walk**	222	230		
No			128 (58)	162 (70)
Yes			94 (42)	68 (30)
Difficulty going from sitting to standing***	222	230		
No			47 (21)	86 (37)
Yes			175 (79)	144 (63)
Total activity difficulties (max.5)***	222	230		
Less than 3			82 (37)	134 (58)
3 or greater			140 (63)	96 (42)

Table 8.7c (continued)

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
Neck pain**	222	230		
No			168 (76)	149 (65)
Yes			54 (24)	81 (35)
Head pain	222	230		
No			214 (96)	220 (96)
Yes			8 (4)	10 (4)
Shoulder or arm pain***	222	230		
No			179 (81)	153 (67)
Yes			43 (19)	77 (33)
Leg pain above the knee only	221	230		
No			162 (73)	179 (78)
Yes			59 (27)	51 (22)
Leg pain below the knee*	221	230		
No			183 (83)	174 (76)
Yes			38 (17)	56 (24)
Of those with leg pain*	97	144		
Constant			15 (15)	39 (27)
Intermittent			82 (85)	105 (73)
Widespread pain	221	230		
No areas			80 (36)	60 (26)
1 area			97 (44)	92 (40)
2 areas			31 (14)	54 (24)
> 2 areas			13 (6)	24 (10)
Treated by this chiropractor before	221	229		
Yes			60 (27)	55 (24)
No			161 (73)	174 (76)
Recovery expectation for current episode***	219	220		
Full			159 (73)	122 (55)
Partial			57 (26)	86 (39)
Probably not			2 (< 1)	11 (5)
Definitely not			1 (< 1)	1 (1)

Table 8.7c (continued)

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
First ever LBP episode	221	228		
Never before			27 (12)	26 (11)
Within the past year			19 (9)	23 (10)
1-5 years ago			59 (27)	62 (27)
5-10 years ago			38 (17)	46 (20)
> 10 years ago			72 (32)	66 (30)
Cannot remember			6 (3)	5 (2)
LBP over the past 12 months* **	187	202		
≤ 30 days intermittent			136 (73)	68 (34)
≤ 30 days constant			22 (12)	3 (1)
> 30 days intermittent			23 (12)	91 (45)
> 30 days constant			6 (3)	40 (20)

* p < 0.1; ** p < 0.05; *** p < 0.001 (Chi-square test)

Table 8.8 Description of the Bournemouth Questionnaire (BQ) sub-scale and total scores at baseline in participating acute (n = 222) and subacute/chronic (n = 230) low back pain patients

BQ scores	Number		Mean (SD)		*p-value
	Acute	Subacute/ chronic	Acute	Subacute/ chronic	
Pain	222	229	6.5 (2.02)	5.6 (2.19)	< 0.001
Disability in activities of daily living	222	229	6.4 (2.61)	4.7 (2.79)	< 0.001
Disability in social activities	220	229	6.0 (2.87)	4.4 (3.04)	< 0.001
Anxiety	221	228	5.1 (2.17)	4.5 (2.80)	0.015
Depression	222	228	3.3 (2.93)	3.2 (2.75)	0.732
Work fear-avoidance beliefs	222	228	5.5 (3.05)	4.8 (2.98)	0.030
Locus of control	221	227	5.2 (2.33)	4.8 (2.70)	0.095
Total score	219	224	38.1(13.76)	32.2 (14.42)	< 0.001

*independent samples t-test

Table 8.9 Description of clinical examination findings of participating acute (n = 222) and subacute/chronic (n = 230) low back pain patients

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
Type of onset* **	221	224		
Sudden			156 (71)	73 (33)
Gradual			65 (29)	151 (67)
Mode of onset* **	215	222		
Trauma			26 (12)	25 (11)
Effort			101 (47)	57 (26)
Insidious			78 (36)	125 (56)
Other			10 (5)	15 (7)
LBP localised to one side	217	224		
Yes			132 (61)	123 (55)
No			85 (39)	101 (45)
LBP in flexion* **	211	214		
No			70 (33)	119 (56)
Yes			141 (67)	95 (44)
LBP in extension	211	214		
No			77 (36)	82 (38)
Yes			134 (64)	132 (62)
LBP in lateral flexion **	211	214		
No			79 (37)	103 (48)
Yes			132 (63)	111 (52)
LBP in rotation	211	214		
No			127 (60)	140 (65)
Yes			84 (40)	74 (35)
Painful catch during movement*	214	222		
Yes			92 (43)	72 (33)
No			123 (57)	146 (66)
Test not done			1 (< 1)	3 (1)
Pain on palpation*	214	222		
Yes			178 (83)	168 (76)
No			36 (17)	54 (24)
Leg pain **	221	225		
Yes			70 (32)	96 (43)
No			151 (68)	129 (57)

Table 8.9 (continued)

Variable	Number of patients		Number (percentage)	
	Acute	Subacute/chronic	Acute	Subacute/chronic
Of those with leg pain, positive nerve root signs	77	93		
Yes			28 (36)	30 (32)
No			42 (55)	56 (60)
Possibly			6 (8)	6 (7)
Test not done			1 (1)	1 (1)
Of those with leg pain, pain with repeated flexion	76	96		
Yes			5 (7)	14 (15)
No			20 (26)	31 (32)
Test not done			51 (67)	51 (53)
Of those with leg pain, pain with repeated extension	76	96		
Yes			5 (7)	4 (4)
No			20 (26)	35 (36)
Test not done			51 (67)	57 (60)
Pain lingers after physical examination	214	222		
Yes			74 (35)	68 (31)
No			140 (65)	154 (69)
Immediate improvement following treatment	204	218		
Yes			142 (70)	136 (62)
No			58 (28)	80 (37)
Not treated today			4 (2)	2 (1)
Recovery expectation at 3 months by chiropractor* **	217	223		
Fully recovered			166 (76)	114 (51)
Partially recovered			43 (20)	88 (39)
Not sure			8 (4)	21 (10)

Table 8.9 (continued)

Variable	Number of patients		Mean (SD)		Median (25^{th}, 75^{th})	
	Acute	Sa/chronic	Acute	Sa/chronic	Acute	Sa/chronic
Chiropractor's rating of patient's physical constitution (0 – 10)	218	223	7.2 (1.8)	7.2 (1.8)	8 (6, 9)	8 (6, 9)
Chiropractor's rating of patient's mental/emotional resilience (0 – 10)	218	223	7.6 (1.8)	7.4 (1.8)	8 (7, 9)	8 (6, 9)

0 = very fragile; 10 = very robust
Sa/chronic = subacute/chronic
* $p < 0.1$; ** $p < 0.05$; *** $p < 0.001$ (Chi-square test)

Table 8.10 Description of the patient-practitioner relationship in participating acute (n = 222) and subacute/chronic (n = 230) low back pain patients

Variable	Number of patients		Mean (SD)		Median (25^{th}, 75^{th})	
	Acute	Sa/chronic	Acute	Sa/chronic	Acute	Sa/chronic
Enough time with the chiropractor (0 – 7)	220	226	1.3 (2.4)	1.6 (2.4)	1 (0, 1)	0 (0, 2)
The chiropractor understands and can help me (0 – 7)	220	227	0.9 (2.2)	0.9 (2.0)	0 (0, 0)	0 (0, 1)
Agreed lifestyle changes (0 – 7)	196	212	0.9 (2.0)	0.9 (1.9)	0 (0, 1)	0 (0, 1)
Shared understanding of treatment goals (0 – 7)	206	218	1.0 (2.1)	1.0 (2.0)	0 (0, 1)	0 (0, 1)

0 = strongly agree; 7 = strongly disagree
Sa/chronic = subacute/chronic

8.2 Responders and non-responders at each outcome measurement point

8.2.1 Short term outcome: text-messaging study

In the immediate short term, outcome data were recorded *via* text message on a daily basis for 7 days following the initial consultation and comprised 2 consecutive questions enquiring about 1) average level of pain over the preceding 24 h, and 2) global improvement.

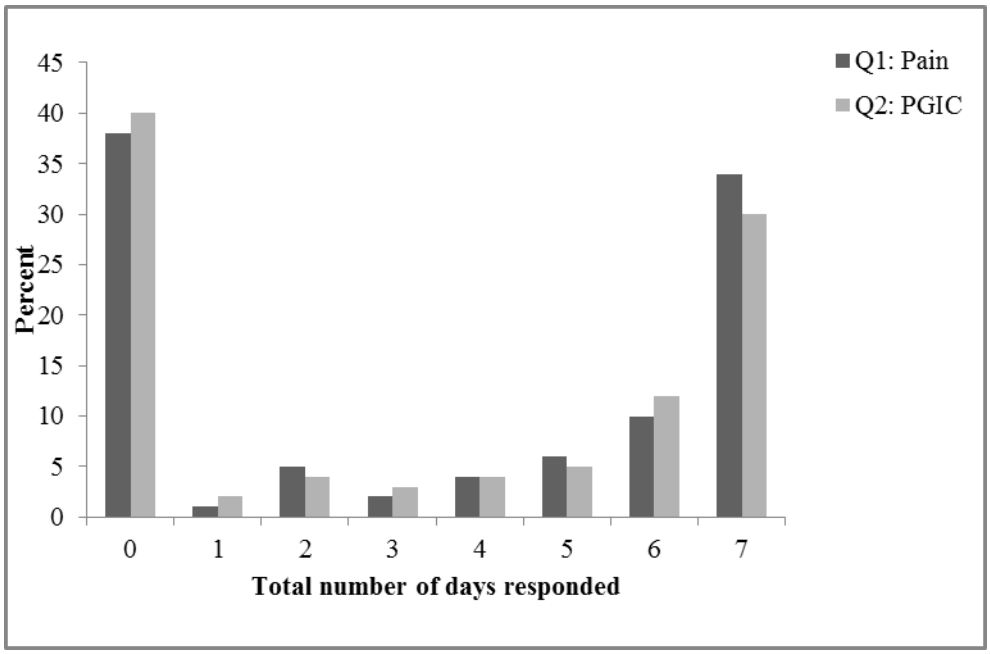
Text-messaging study: responders and non-responders

One hundred and thirty seven (62%) acute and 143 (62%) subacute/chronic LBP patients participated in the text-messaging study by responding to one or more of the text message questions during the 7-day period. The sociodemographic characteristics of the responders were broadly similar to those patients who did not reply to the SMS questions. The mean age of the acute patient responders and non-responders was 41.8 (SD 9.5) and 40.6 (SD 10.5) years respectively. Of the acute patients, 52% of those who replied and 65% of those who did not were males. The subacute/chronic responders had a mean age of 41.8 (SD 10.4) years as compared to a mean age of 39.8 (SD 9.7) years in the non-responder group. Furthermore, the gender distribution was approximately equal as 48% of responders and 54% of non-responders were males. There were no statistically significant differences in age or gender between responders and non-responders in either duration subgroup.

Of those patients who participated in the SMS study for the entire 7 day period, 76 (34%) were acute and 101 (44%) were subacute/chronic patients. The mean age of these patients (acute: 42.3 years [SD 9.9]; subacute/chronic 41.5 years [SD 10.0]) was broadly similar to those patients who failed to respond (acute: 40.6 years [SD 10.5]; subacute/chronic: 39.8 years [SD 9.7]). In the acute patient subgroup, there was a statistically significant difference ($\chi^2 = 5.66$ [$p = 0.017$]) in gender distribution between the 7-day responders (52% males) and the non-responders (65% males). There was no statistically significant difference in gender distribution in the subacute/chronic patients

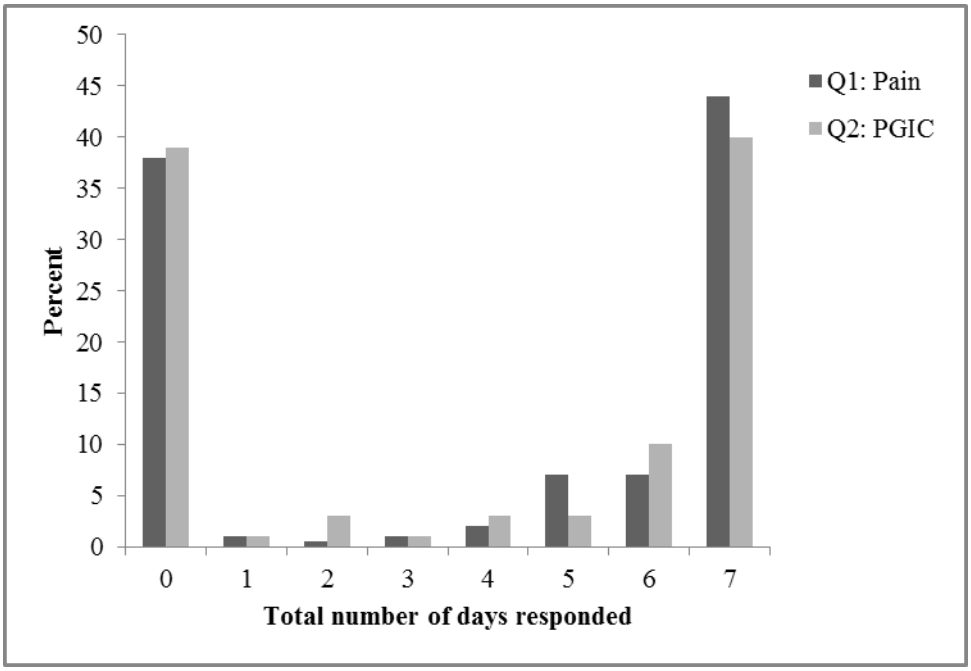
who responded for all 7 days (45% males) compared with the non-responders (54% males).

As presented in Figure 8.5a, approximately 30% of the acute patients replied to both text message questions for all 7 days (34% to question 1; 30% to question 2), whereas approximately 40% failed to respond to any of the SMS question for the entire duration of the SMS study. A similar pattern is seen in Figure 8.5b for the subacute/chronic patients, with the majority either answering for the entire 7 days (approximately 40%) or not at all (approximately 39%). A greater proportion of the subacute/chronic compared to acute patients responded for the entire 7-day period (Figure 8.5a and 8.5b). As the text message questions were sent to participating patients on a daily basis over 7 days, it was not feasible to send text message reminders to the non-responders.



PGIC = patient's global impression of change

Figure 8.5a Percentage distribution of the total number of days acute LBP patients (n = 222) responded to the SMS questions (pain and PGIC)



PGIC = patient's global impression of change

Figure 8.5b Percentage distribution of the total number of days subacute/chronic LBP patients (n = 230) responded to the SMS questions (pain and PGIC)

Text-messaging daily response rates to Questions 1 and 2

As shown in Figure 8.6a, approximately half of all acute (55%) and subacute/chronic (57%) patients replied to Question 1 on Day 1 (the day following the 1st visit) enquiring about the level of pain associated with their low back complaint. The number of responders to this question gradually declined over the 7 days in both patient groups (Figure 8.6a). However, this decline was more marked in the acute group (8%) compared with the subacute/chronic participants (3%). All SMS responses received to Question 1 from both subgroups were valid and therefore included in the data analysis.

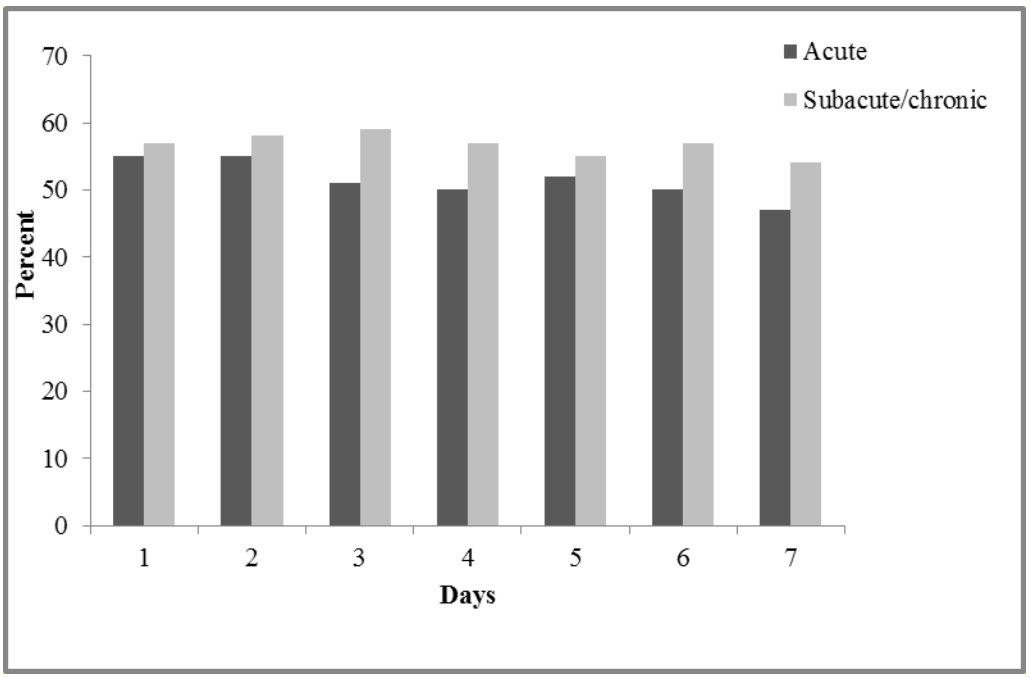


Figure 8.6a Percentage distribution of the response rates to SMS Question 1 (pain) in acute (n = 222) and subacute/chronic (n = 230) LBP patients on each of the 7 days

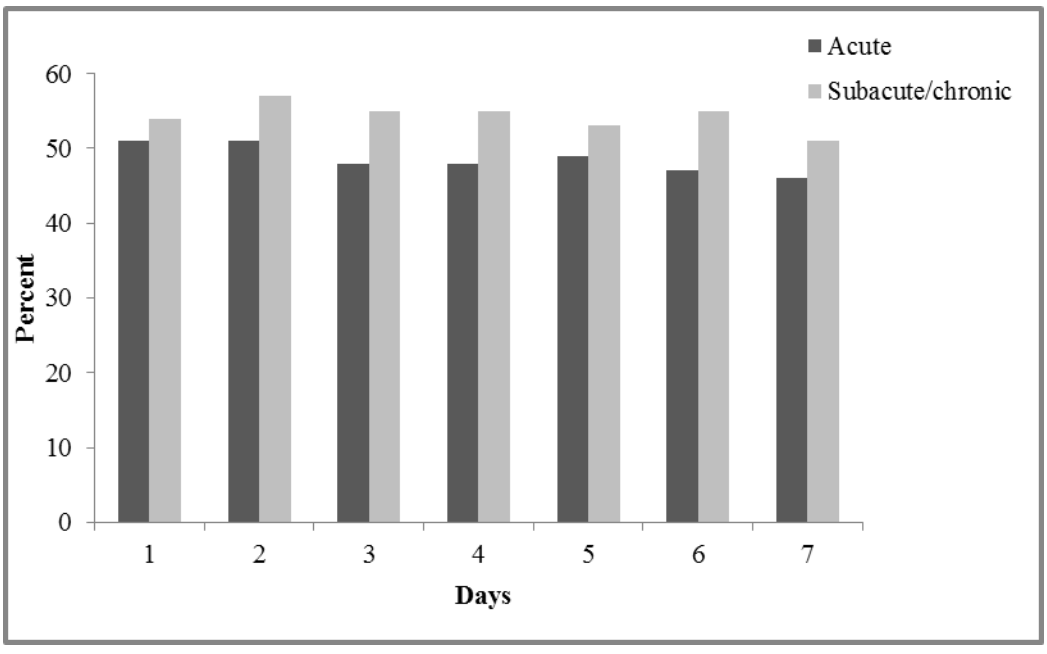


Figure 8.6b Percentage distribution of the response rates to SMS Question 2 (PGIC) in acute (n = 222) and subacute/chronic (n = 230) LBP patients on each of the 7 days

Question 2 required patients to rate the global improvement for their LBP. On Day 1, approximately 50% of patients (acute 51%, subacute/chronic 55%) responded. By Day 7 the PGIC response rates resembled those of Question 1 (pain) with a 5% and 3% decrease in the acute and subacute/chronic groups respectively (Figure 8.6b). Although the SMS responses to the PGIC were recorded over 7 consecutive days, difficulties with the phrasing of this question were only recognised at this stage thereby resulting in feasible analysis of the PGIC data solely from Day 1. The rationale for this management of the data is expanded further in the Discussion (Chapter 9). As shown in Table 8.11, there was a statistically significant correlation between pain and the PGIC at each outcome measurement point in both duration subgroups. There was a positive correlation between these variables and the correlation coefficient was at a consistently moderate level (r = 0.4-0.6) at each follow-up point (Table 8.11).

Table 8.11 Correlation between PGIC and pain change scores at Day 1, 4th visit, 3 months and 6 months in acute and subacute/chronic LBP patients

PGIC scores and pain change scores	Acute		Subacute/chronic	
	Correlation coefficient (r)	p-value	Correlation coefficient (r)	p-value
Day 1	.422	< 0.001	.493	< 0.001
4th visit	.457	< 0.001	.473	< 0.001
3 months	.419	< 0.001	.616	< 0.001
6 months	.414	< 0.001	.404	< 0.001

r = Spearman's correlation coefficient

Following data clean-up, one SMS reply to the PGIC on Day 1 from an acute LBP patient was discarded due to an invalid numerical response; however, all responses received from the subacute/chronic patients were valid and therefore included in the data analysis.

8.2.2 Short term outcome: 4th visit

Of the 222 acute LBP patients, 148 (66%) returned to the chiropractic clinic for their 4th visit (or at an earlier visit if treatment was concluded sooner) and completed the follow-up questionnaire, all of which were valid. One hundred and seventy-seven subacute/chronic patients (77% of 230) attended the 4th visit and following data cleaning, all questionnaires were valid and therefore included in the data analysis.

In the acute subgroup, the mean age of the patients that attended the 4th visit was 41.5 (SD 10.0) years and this closely resembled those that failed to return (41 [SD 9.59] years). Furthermore, 57% of both responders and non-responders in the acute subgroup were males. Of the responders among the subacute/chronic patients, the mean age was 41.5 (SD 9.77) years, compared to 39.7 (SD 11.25) years of the non-responders at the 4th visit. Fifty-two percent of responders and 44% of non-responders were males. There was no statistically significant difference in age or gender between responders and non-responders in either the acute or subacute/chronic cohorts at the 4th visit.

The range of days between the 1st and 4th chiropractic treatment extended from 3 to 76 days in the acute and 2 to 78 days in the subacute/chronic cohorts. The mean number of days to the 4th visit for the acute and subacute/chronic patients was 18.2 (SD 12.9) and 19.2 (SD 11.8) days respectively. As shown in Figure 8.7, the vast majority of patients received their 4th treatment within 28 days of their initial consultation, with the greater proportion in both subgroups (51% acute, 46% subacute/chronic) returning within 2 weeks. Thereafter, there was a steady decrease in the number of patients returning for their 4th visit at each of the successive time intervals.

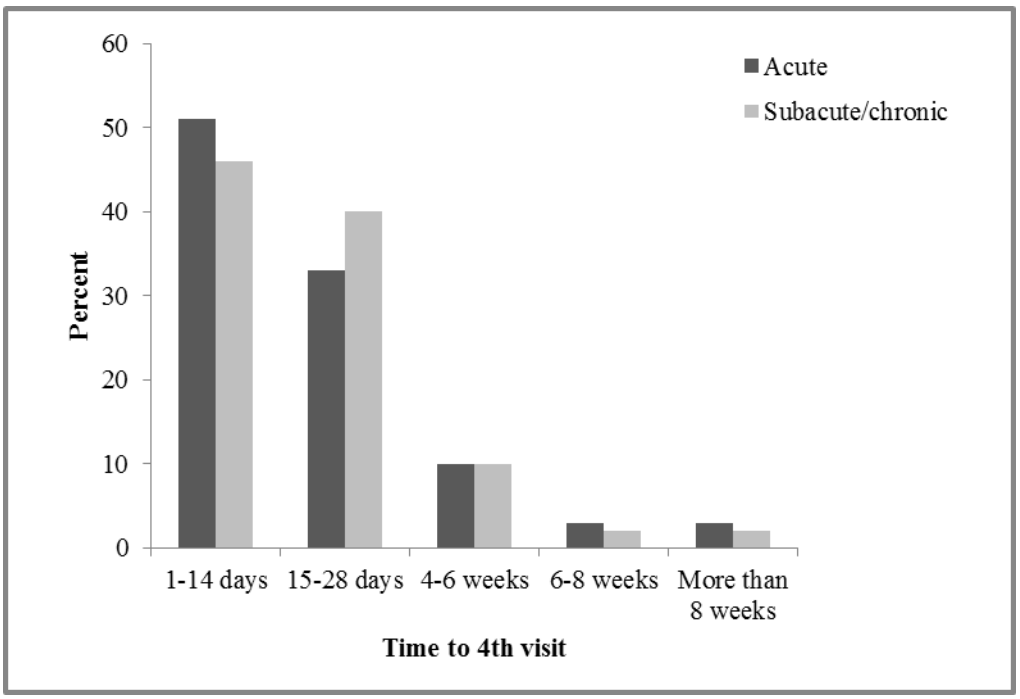


Figure 8.7 Percentage distribution of time to the 4th visit for the acute (n = 148) and subacute/chronic (n = 177) patients

Thirty-four percent of acute patients and 23% of subacute/chronic patients failed to return to the chiropractic clinic for their scheduled 4th treatment. The chiropractors had been instructed to document the reason (if known) why a patient did not return for the follow-up visit and to contact the patient directly to retrieve this information if necessary. During data cleaning, reasons for the missed 4th appointment were assigned to one of 7 categories, the distribution of which is shown in Figure 8.8. The reason cited by the majority of chiropractors (on behalf of the patients) for missing the 4th visit was 'unknown' (50% acute patients, 57% subacute/chronic patients) followed by the category of 'better, not necessary' (28% acute, 13% subacute/chronic).

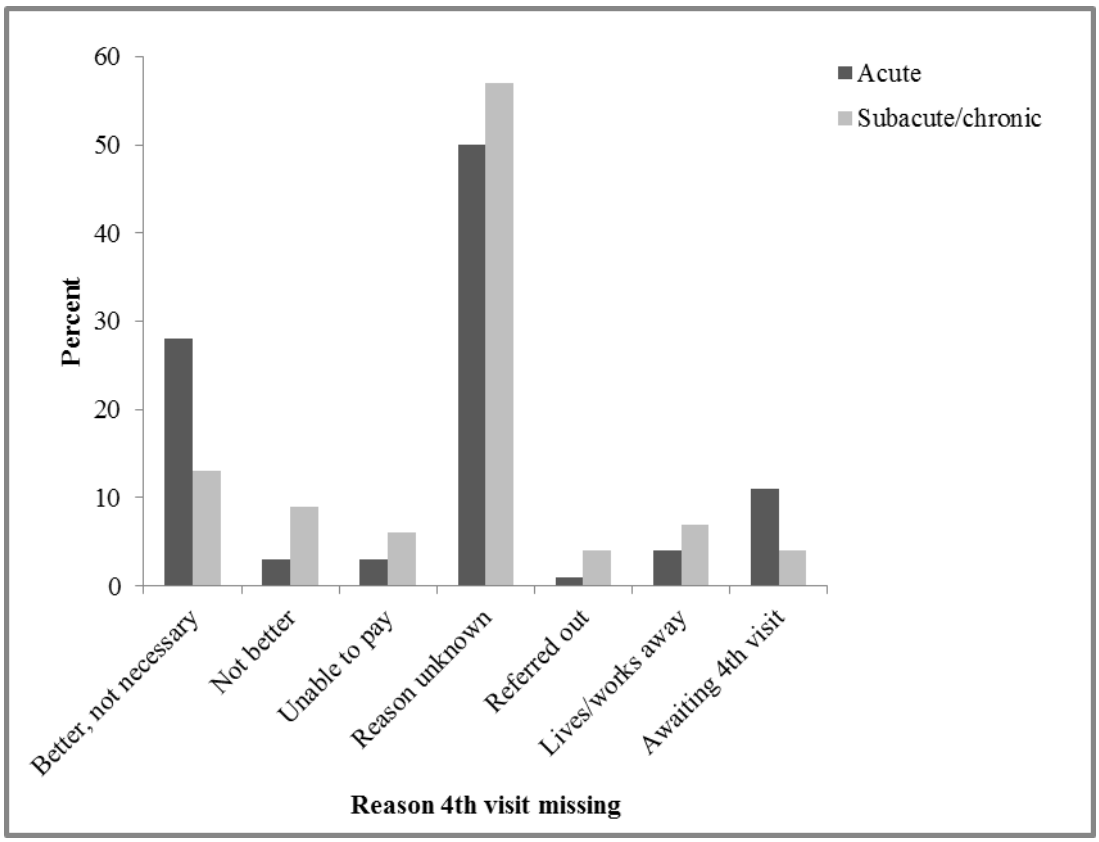


Figure 8.8 Percentage distribution of the reasons that acute patients (n = 74) and subacute/chronic patients (n = 53) did not attend 4th visit

8.2.3 Medium and long term outcome: 3 months and 6 months

Eighty-nine (40%) acute patients returned completed questionnaires at 3 months, 88 of which were valid. Similarly, 95 (41%) questionnaires were returned by the subacute/chronic patients, none of which were discarded during data cleaning. The mean age of the responders in the acute group was 44.4 years (SD 9.90) whereas the mean age of non-responders was significantly lower (38.7 years [SD 9.68]; $p < 0.001$). However, there was an approximately equal gender distribution as 52% of responders and 59% of non-responders were males. Among the subacute/chronic patients that returned the questionnaire at 3 months, the mean age was 44.4 years (SD 9.90), compared to a significantly different mean age of 38.7 (SD 9.68) years for those that did not respond ($p < 0.001$). Furthermore, there was a statistically significant difference in

gender distribution as 33% of responders and 50% of non-responders in the subacute/chronic cohort were males ($p < 0.02$).

A system of SMS reminders was utilised for the 3 months postal questionnaires. The SMS reminder system had been instigated prior to completion of data collection and hence prior to dividing the whole cohort into acute and subacute/chronic patient subgroups. The SMS reminders were assigned to 2 groups. In the first group, 106 consecutive patients received a SMS reminder if they had failed to return the questionnaire within 2 weeks of receipt (the post-reminder group). The second group comprised 100 consecutive patients who were alerted by SMS prior to the arrival of the questionnaire (the pre-reminder group).

Of the 106 SMS post-reminders dispatched, 16 (15%) patients responded by returning the 3 month questionnaire whereas in the pre-reminder group, 43 patients (43%) successfully returned completed questionnaires (Figure 8.9). However, in a group of 100 consecutive patients who did not receive a reminder (the no reminder group), 46% returned the 3 month questionnaire. As shown in Figure 8.9, there was an increase of 27% in the response rate if a patient was alerted prior to receiving the questionnaire (pre-reminder group) compared with a reminder to complete the received questionnaire (post-reminder group). However, these response rates were still less than those who did not receive either alert or reminder (no reminder group).

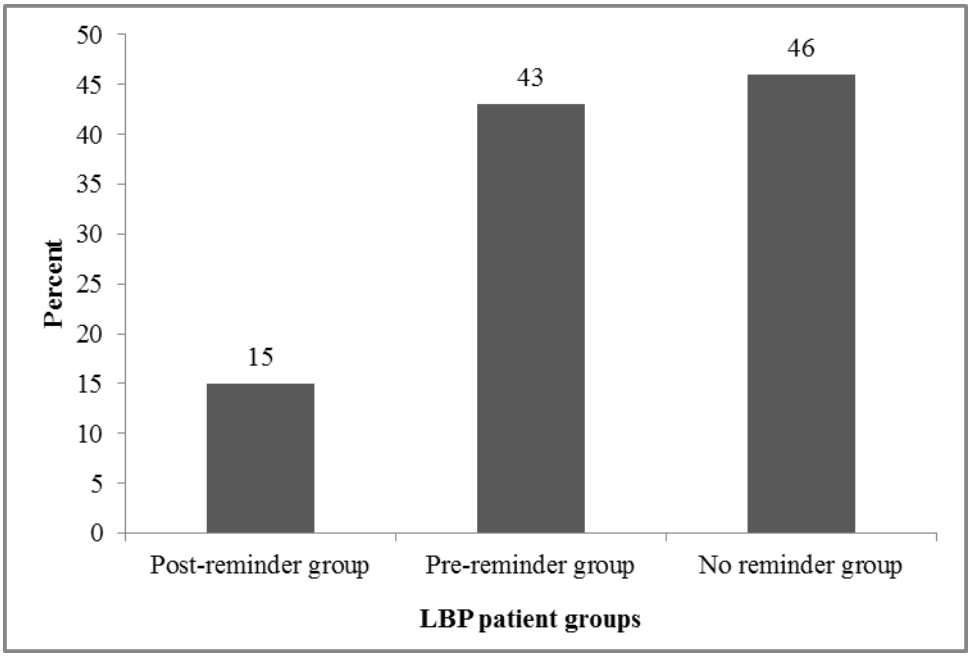


Figure 8.9 Percentage distribution of the response rates in the text message post-reminder (n = 106), pre-reminder (n = 100) and no reminder groups (n = 100) for the postal questionnaire at 3 months

At 6 months, all 75 (33%) of the questionnaires returned by the acute patients were found to be valid following data cleaning. Of the subacute/chronic patients, 74 questionnaires were returned and of these, 73 (32%) were eligible for data analysis. In the acute patient group, there was a statistically significant difference between the responders and non-responders in age (45.5 years [SD 8.83] and 39.3 years [SD 9.73] respectively; $p < 0.001$) but not in gender distribution (51% of responders and 60% of non-responders were males). Moreover, a similar pattern emerged in the subacute/chronic group, as the mean age of the responders differed significantly from the non-responders (44.2 years [SD 10.17] and 39.6 years [SD 9.82] respectively; $p < 0.001$), whereas there was no significant difference in gender distribution (44% and 53% of responder and non-responders were males).

8.3 Outcomes

8.3.1 Outcomes in the short term: text-messaging study

Outcomes in the short term comprised pain and global improvement recorded *via* SMS. The SMS mean pain scores (Question 1) for the acute and subacute/chronic patients over the 7 day period are presented in Table 8.12. In both duration subgroups there was a decline in the mean pain scores from Day 1 to Day 7 and this was of a greater magnitude in the acute compared to the subacute/chronic cohort. There was no statistically significant difference in the mean pain scores between the duration subgroups on any of the 7 days (Table 8.12). In contrast, the mean difference in pain scores between each successive day was statistically significant in both the duration subgroups with the exception Day 1 to Day 2 in the subacute/chronic cohort (Table 8.13).

Table 8.12 SMS pain scores (mean values) from Day 1 to Day 7 in acute (n = 76) and sub-acute/chronic (n = 101) LBP patients

SMS pain scores	Number		Mean (SD)		*p-value
	Acute	Subacute/ chronic	Acute	Subacute/ chronic	
Day 1	76	101	5.0 (2.14)	4.7 (1.91)	0.250
Day 2	76	101	4.2 (1.96)	4.2 (2.12)	0.926
Day 3	76	101	3.7 (1.85)	3.8 (2.11)	0.771
Day 4	76	101	3.3 (1.88)	3.6 (2.05)	0.321
Day 5	76	101	2.9 (1.79)	3.4 (1.99)	0.123
Day 6	76	101	2.7 (1.86)	3.1 (1.91)	0.133
Day 7	76	101	2.5 (1.94)	3.0 (2.00)	0.095

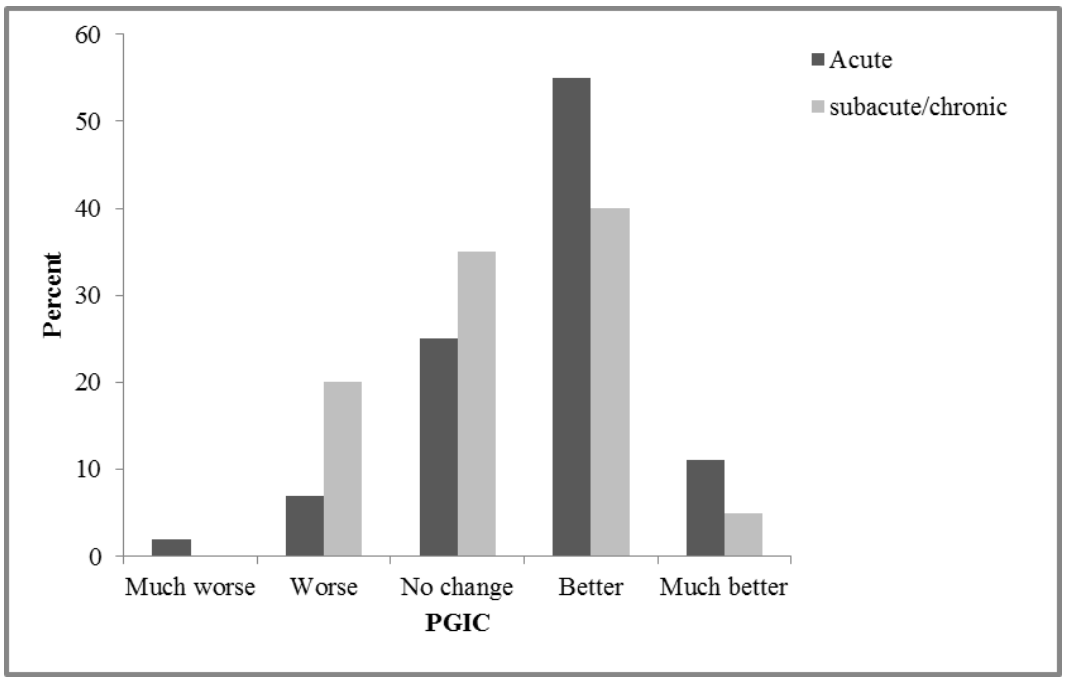
* between group independent samples t-test

Table 8.13 Within-group mean change from Day 1 in daily SMS pain scores in acute (n = 76) and subacute/chronic (n = 101) LBP patients

Follow-up	Acute Mean change (95% CI)	Subacute/chronic Mean change (95% CI)
Day 2	0.79 (0.3-1.3) *	0.47 (0.06-0.99)
Day 3	1.30 (0.7-1.9) *	0.86 (0.2-1.5) *
Day 4	1.78 (1.1-2.5) *	1.11 (0.5-1.8) *
Day 5	2.08 (1.4-2.7) *	1.28 (0.6-1.9) *
Day 6	2.33 (1.7-3.0) *	1.54 (0.9-2.2) *
Day 7	2.50 (1.8-3.2) *	1.64 (1.0-2.3) *

CI = confidence interval; * GLM repeated measures = mean change is significant $p \leq 0.05$,

Of the 5 possible responses to the PGIC on Day 1 ranging from 1) 'much worse' to 5) 'much better', 11% of acute and 5% of subacute/chronic patients respectively reported that their LBP was much better; 55% and 40% rated their complaint as better; 25% and 35% stated that there was no change and 7% and 20% of acute and subacute/chronic patients reported that their LBP was worse (Figure 8.10) The response 'much worse' was reported only by a minority (2%) of acute patients.



PGIC = patient's global impression of change

Figure 8.10 Percentage distribution of the SMS patient's global impression of change (PGIC) scale responses on Day 1 in acute (n = 112) and subacute/chronic (n = 126) patients

The responses to the text message PGIC were subsequently dichotomised into 'improved' and 'not improved'. Patients who replied with a number ranging from 1 to 4 were classified as not improved; those who answered with the number 5 ('much better') were categorised as improved (Table 8.14). On Day 1, there was no statistically significant difference in numbers of patients categorised as improved between the acute and subacute/chronic subgroups.

Table 8.14 Numbers of improved and not improved acute and subacute/chronic patients as categorised by the dichotomised patient's global impression of change (PGIC) scale on Day 1

PGIC	Acute Number (%)	Improved (%)	Not improved (%)	Subacute/chronic Number (%)	Improved (%)	Not improved (%)
Day 1	112 (51)	12 (11)	100 (89)	126 (55)	6 (5)	120 (95)

8.3.2 Outcomes in the short, medium and long term

Outcomes documented in the medium and long terms (at the 4th visit, 3 months and 6 months) comprised the PGIC, the BQ, difficulties experienced with specific daily activities (Nordic questions), and return to work status.

8.3.2.1 Outcomes reported at the 4th visit

Patient's Global Impression of Change (PGIC) at the 4th visit

The PGIC responses were subsequently dichotomised into 'improved' and 'not improved'. Patients who selected a response corresponding to descriptors 1 to 6 were categorised as not improved; the 7th and 8th responses equated to meaningful improvement. As presented in Table 8.15, 82% of acute compared to 61% of subacute/chronic patients were categorised as improved at the 4th visit, and this difference was highly statistically significant ($\chi^2 = 16.64$; $p < 0.001$).

Table 8.15 Improved and non-improved acute and subacute/chronic patients as categorised by the dichotomised patient's global impression of change (PGIC) scale at the 4th visit

PGIC	Acute Number (%)	Improved (%)	Not improved (%)	Subacute/chronic Number (%)	Improved (%)	Not improved (%)
4th visit	146 (66)	119 (82)	27 (18)	175 (76)	106 (61)	69 (39)

Table 8.16 presents the number and percentage distribution of the 8 possible responses to the PGIC in acute and subacute/chronic patients at the 4th visit, ranging from 1) 'worse' to 8) 'a great deal better and a considerable improvement that has made all the difference'. Of these 8 responses, the 7th descriptor of 'better and a definite improvement that has made a real and worthwhile difference' was reported most frequently by patients in both groups (42% acute, 37% subacute/chronic) at the 4th visit.

Table 8.16 Distribution of the responses to the patient's global impression of change (PGIC) scale in acute and subacute/chronic patients at 4th visit, 3 months and 6 months

PGIC Responses (1 to 8)	4th visit		3 months		6 months	
	Acute (n = 146)	Subacute/chronic (n = 175)	Acute (n = 87)	Subacute/chronic (n = 95)	Acute (n = 73)	Subacute/chronic (n = 73)
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
1. Worse	2 (1)	4 (2)	1 (1)	5 (5)	0 (0)	4 (6)
2. No Change	0 (0)	6 (3)	3 (3)	4 (4)	2 (3)	7 (10)
3. Almost the same, hardly any change	2 (1)	7 (4)	2 (2)	6 (6)	1 (1)	2 (3)
4. A little better but no noticeable change	3 (2)	9 (5)	0 (0)	1 (1)	1 (1)	1 (1)
5. Somewhat better but the change has made no real difference	1 (< 1)	7 (4)	1 (1)	4 (4)	2 (3)	1 (1)
6. Moderately better and a slight but noticeable difference	19 (13)	36 (21)	5 (6)	13 (14)	3 (4)	6 (8)
7. Better and a definite improvement that has made a real and worthwhile difference	60 (42)	64 (37)	36 (42)	38 (40)	25 (34)	27 (37)
8. A great deal better and a considerable improvement that has made all the difference	59 (41)	42 (24)	39 (45)	24 (26)	39 (54)	25 (34)

Bournemouth Questionnaire (BQ) at the 4th visit

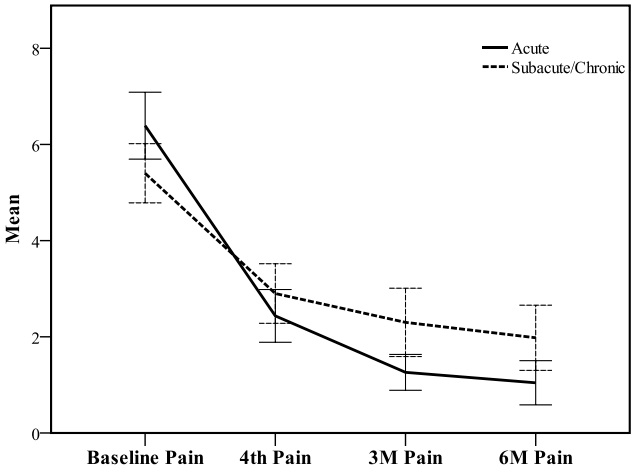
The BQ sub-scale and total scores (mean values) at the 4th visit for the subgroups are presented in Table 8.17. The mean values for the sub-scales and total score in the acute group were all equal to or lower than those of the subacute/chronic group with the exception of the work fear-avoidance beliefs sub-scale, which was of a marginally higher value in the acute patients. There were no statistically significant differences between the two cohorts, with the exception of depression and locus of control sub-scales. Furthermore, as illustrated in Figure 8.11, there was a decrease in all BQ sub-scale and total mean scores at the 4th visit in both patient groups compared to the mean scores at baseline.

Table 8.17 Bournemouth Questionnaire sub-scale and total scores (mean values) at 4th visit for acute (n = 148) and subacute/chronic (n = 177) patients

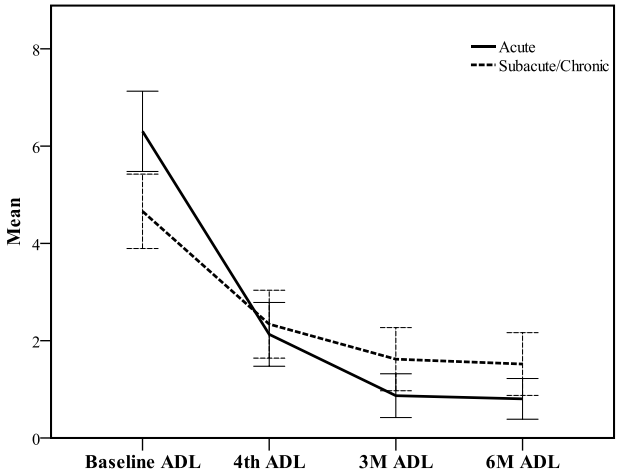
BQ scores	Number		Mean (SD)		*p-value
	Acute	Subacute/ chronic	Acute	Subacute/ chronic	
Pain	148	177	2.4 (2.06)	2.8 (2.03)	0.088
Disability in activities of daily living	148	177	2.3 (2.37)	2.3 (2.28)	0.866
Disability in social activities	148	177	2.2 (2.65)	2.2 (2.41)	0.883
Anxiety	148	177	2.0 (2.37)	2.4 (2.34)	0.102
Depression	148	177	1.3 (2.08)	1.8 (2.29)	0.049
Work fear-avoidance beliefs	148	177	2.5 (2.73)	2.4 (2.51)	0.858
Locus of control	146	173	1.9 (2.11)	2.5 (2.26)	0.012
Total score	146	173	14.9 (14.20)	16.7 (13.19)	0.241

*independent samples t-test

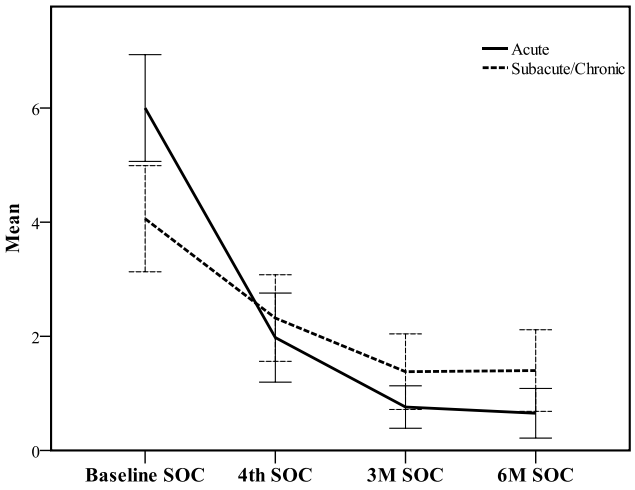
BQ Pain



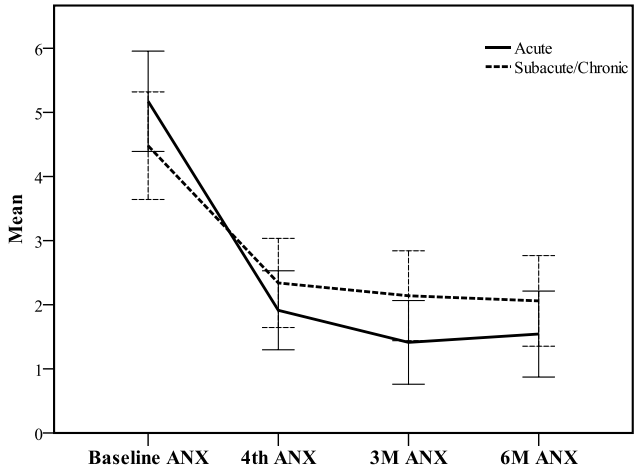
BQ Disability in activities of daily living (ADL)



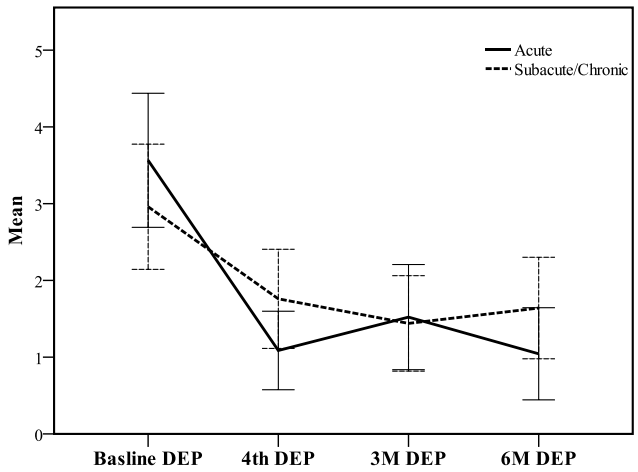
BQ Disability in social activities (SOC)



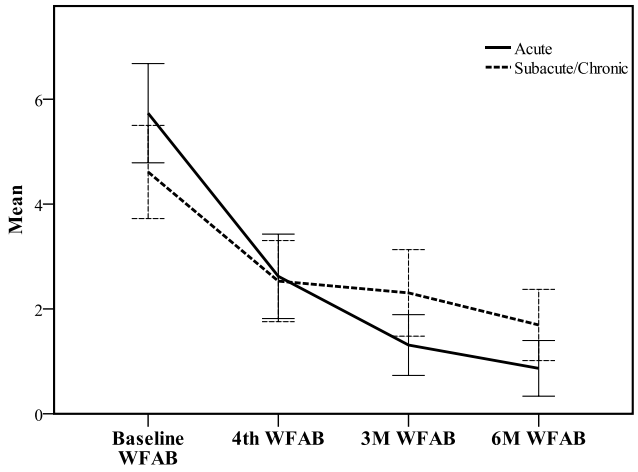
BQ Anxiety (ANX)



BQ Depression (DEP)



BQ Work fear-avoidance beliefs (WFAB)



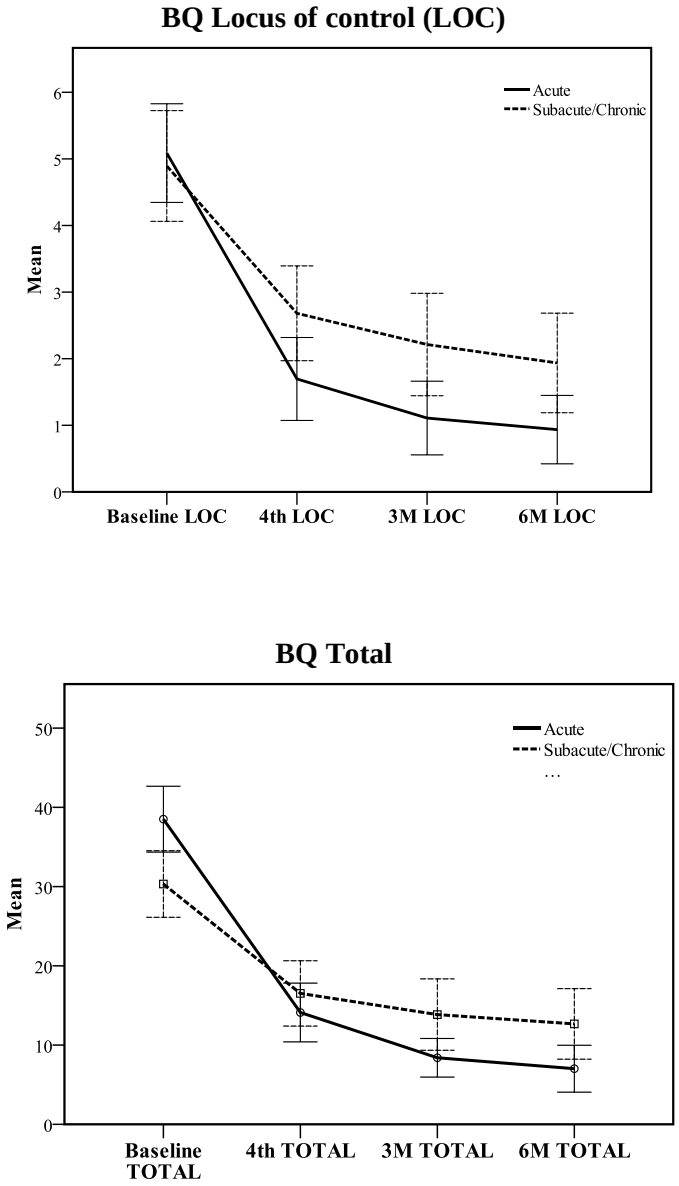


Figure 8.11 Bournemouth Questionnaire sub-scale and total scores (mean values) at baseline, 4th visit, 3 months and 6 months in acute and subacute/chronic patients
(error bars: 95% confidence intervals)

Difficulties with daily activities at the 4th visit

At the 4th visit, difficulties recorded with specific daily activities (Nordic questions) due to LBP are shown in Table 8.18. Of these five activities, difficulty going from sitting to standing was the greatest problem experienced by the acute patients, whereas turning in bed was difficult for the majority of the subacute/chronic group. In both of the patient groups, the activity that caused the least difficulty was going for a walk.

Table 8.18 Description of difficulties with daily activities (Nordic questions) at the 4th visit in acute and subacute/chronic patients

Difficulties with daily activities (Nordic questions)	4th visit		
	Acute (n = 146)	**Subacute/chronic** (n = 175)	***p-value**
Difficulty turning in bed	41 (28)	68 (40)	0.042
Difficulty sleeping	28 (19)	49 (28)	0.065
Difficulty putting on socks or shoes	48 (33)	54 (31)	0.699
Difficulty going for a walk	20 (14)	29 (17)	0.476
Difficulty going from sitting to standing	50 (34)	67 (38)	0.454

Values are numbers (percentages)
*Chi-square test

Return to work status at the 4th visit

Of the acute patients who responded at the 4th visit, 19% (26/140) of those who had previously taken sick leave due to LBP had returned to work. In the subacute/chronic patient group, 7% (12/168) reported that they had returned to work following LBP-related absence.

8.3.2.2 Outcomes reported at 3 months

Patient's Global Impression of Change (PGIC) at 3 months

For the PGIC at 3 months, the majority of acute (87%) and subacute/chronic patients (66%) reported the 7th and 8th descriptors of 'better and a definite improvement that has made a real and worthwhile difference' and 'a great deal better and a considerable improvement that has made all the difference' (Table 8.15) and were therefore categorised as improved (Table 8.19). The difference between those acute and subacute/chronic patients who reported meaningful improvement at 3 months was highly significant ($\chi^2 = 10.70$; $p < 0.001$).

Table 8.19 Improved and non-improved acute and subacute/chronic patients as categorised by the dichotomised patient's global impression of change (PGIC) scale at 3 months

PGIC	Acute Number (%)	Improved (%)	Not improved (%)	Subacute/chronic Number (%)	Improved (%)	Not improved (%)
3 months	87 (39)	75 (86)	12 (14)	95 (41)	62 (65)	33 (35)

Bournemouth Questionnaire (BQ) at 3 months

The BQ sub-scale and total scores (mean values) at 3 months are shown in Table 8.20. In all 7 of the sub-scales and the total score, the mean values were greater in the subacute/chronic than the acute patients. Statistically significant differences ($p < 0.05$) between the groups were present for the BQ total score and all of the sub-scales with the exception of depression. As illustrated in Figure 8.11, all of the BQ scores at 3 months were lower than at baseline in both subgroups.

Table 8.20 Bournemouth Questionnaire sub-scale and total scores (mean values) at 3 months for acute (n = 88) and subacute/chronic (n = 95) patients

BQ scores	Number		Mean (SD)		*p-value
	Acute	Subacute/ chronic	Acute	Subacute/ chronic	
Pain	88	95	1.3 (1.50)	2.3 (2.47)	0.001
Disability in activities of daily living	88	95	0.8 (1.59)	1.7 (2.11)	0.002
Disability in social activities	88	95	0.7 (1.45)	1.6 (2.16)	0.002
Anxiety	88	95	1.4 (2.03)	2.1 (2.45)	0.039
Depression	88	95	1.2 (2.19)	1.5 (2.25)	0.354
Work fear-avoidance beliefs	87	94	1.5 (2.18)	2.4 (2.70)	0.017
Locus of control	88	95	1.2 (2.05)	2.2 (2.35)	0.004
Total score	87	94	8.5 (9.38)	14.0 (14.08)	0.003

*independent samples t-test

Difficulties with daily activities at 3 months

Table 8.21 shows the difficulties experienced by the patient groups in various daily activities. At 3 months, a similar pattern emerged to 4th visit as difficulty going from sitting to standing was reported by the majority of acute and subacute/chronic patients (although the same number of subacute/chronic patients also experienced difficulty turning in bed). Furthermore, the least-reported difficulty in both groups was going for a walk.

Table 8.21 Description of difficulties with daily activities (Nordic questions) at 3 months in acute and subacute/chronic patients

Difficulties with daily activities (Nordic questions)	3 months		
	Acute (n = 88)	**Subacute/chronic** (n = 95)	***p-value**
Difficulty turning in bed	20 (23)	35 (37)	0.037
Difficulty sleeping	13 (15)	25 (26)	0.054
Difficulty putting on socks or shoes	23 (26)	27 (28)	0.729
Difficulty going for a walk	9 (10)	20 (21)	0.045
Difficulty going from sitting to standing	24 (27)	35 (37)	0.166

Values are numbers (percentages)
*Chi-square test

Return to work status and pain-free time at 3 months

At 3 months, 11% (9/82) of the acute and 8% (7/90) of the subacute/chronic patients in paid work who had previously taken sick leave for their LBP reported that they had returned to work. The vast majority of both acute (93%) and subacute/chronic (82%) patients reported that for most or some of the time their low back had been pain-free over the previous 3 months.

8.3.2.3 Outcomes reported at 6 months

Patient's Global Impression of Change (PGIC) at 6 months

From the PGIC at 6 months, a similar pattern to the responses at 3 month emerged as a significantly higher ($\chi^2 = 6.04$; $p < 0.02$) number of acute patients (88%) compared to subacute/chronic patients (71%) responded with the 7^{th} or 8^{th} responses on the PGIC (Table 8.15) and were therefore categorised as improved, as shown in Table 8.22.

Table 8.22 Improved and non-improved acute and subacute/chronic patients as categorised by the dichotomised patient's global impression of change (PGIC) scale at 6 months

PGIC	Acute Number (%)	Improved (%)	Not improved (%)	Subacute/chronic Number (%)	Improved (%)	Not improved (%)
6 months	73 (33)	64 (88)	9 (12)	73 (32)	52 (71)	21 (29)

Bournemouth Questionnaire (BQ) at 6 months

Table 8.23 shows the BQ sub-scale and total scores at 6 months. As at the previous outcome point (3 months), the mean scores for all of the sub-scales and the total score in the acute patients were lower than for the subacute/chronic patient group. Independent samples t-tests resembled the findings at 3 months as only the BQ depression sub-scale score did not differ significantly between the subgroups. In both cohorts, the BQ scores at 6 months were lower than at baseline (Figure 8.11).

Table 8.23 Bournemouth Questionnaire sub-scale and total scores (mean values) at 6 months for acute (n = 75) and subacute/chronic (n = 73) patients

BQ scores	Number		Mean (SD)		*p-value
	Acute	Subacute/ chronic	Acute	Subacute/ chronic	
Pain	75	73	1.2 (1.96)	2.3 (2.50)	0.006
Disability in activities of daily living	75	73	1.0 (1.89)	1.8 (2.50)	0.029
Disability in social activities	75	73	0.8 (1.85)	1.6 (2.65)	0.029
Anxiety	75	73	1.6 (2.28)	2.4 (2.64)	0.040
Depression	75	73	1.2 (2.15)	1.9 (2.35)	0.095
Work fear-avoidance beliefs	73	73	1.0 (1.91)	2.0 (2.64)	0.010
Locus of control	75	72	1.1 (2.01)	2.1 (2.45)	0.009
Total score	73	72	6.7 (9.88)	14.6 (15.52)	0.003

*independent samples t-test

Difficulties with daily activities at 6 months

As for the previous outcome measurement points at the 4th visit and 3 months, the daily activity which resulted in difficulty for the greater proportion of patients in both subgroups was going from sitting to standing (Table 8.24). Difficulty going for a walk was reported by the minority of patients in both cohorts, resembling the findings at each of the previous follow-ups.

Table 8.24 Description of difficulties with daily activities (Nordic questions) at 6 months in acute and subacute/chronic patients

Difficulties with daily activities (Nordic questions)	6 months		
	Acute (n = 75)	**Subacute/chronic** (n = 73)	***p-value**
Difficulty turning in bed	15 (20)	21 (29)	0.214
Difficulty sleeping	6 (8)	16 (22)	0.017
Difficulty putting on socks or shoes	14 (19)	18 (25)	0.376
Difficulty going for a walk	3 (4)	15 (20)	0.002
Difficulty going from sitting to standing	17 (23)	23 (32)	0.226

Values are numbers (percentages)
*Chi-square test

Return to work status and pain-free time at 6 months

For return to work status at 6 months, 7% (5/67) of acute and 6% (4/68) subacute/chronic patients reported that they were no longer on sick leave. Over the previous 3 months, a greater proportion of acute (91%) and subacute/chronic (87%) patients reported that they had been pain-free in their low back.

8.4 Change scores

Change scores were calculated for the SMS Question 1 (pain) from Day 1 to each of the 7 days, and for the BQ (pre-treatment minus post-treatment values) sub-scale and total scores at the 4th visit, 3 months and 6 months.

SMS change scores

The SMS pain changes scores (mean values) are shown in Table 8.25. There was a statistically significant difference ($p < 0.05$) in the magnitude of change in pain between the acute and subacute/chronic patient groups from Day 1 to each of the successive 6 days. Figure 8.12 shows that the extent of change in pain was greater for the acute than for the subacute/chronic patients over the entire 7-day period.

Table 8.25 SMS pain change scores (mean values) from Day 1 to Day 7 in acute (n = 222) and sub-acute/chronic (n = 230) LBP patients

SMS pain change scores	Number		Mean (SD)		* p-value	Mean difference (95% confidence interval)
	Acute	Subacute/ chronic	Acute	Sub-acute/ chronic		
Day 1 to 2	113	126	0.87 (1.57)	0.35 (1.73)	0.017	0.5 (0.09 – 0.9)
Day 1 to 3	106	127	1.46 (1.76)	0.79 (1.94)	0.006	0.6 (0.1 – 1.1)
Day 1 to 4	101	123	1.86 (1.92)	1.10 (2.03)	0.005	0.7 (0.2 – 1.2)
Day 1 to 5	106	121	1.99 (1.81)	1.15 (1.99)	0.001	0.8 (0.3 – 1.3)
Day 1 to 6	103	122	2.37 (1.95)	1.51 (2.05)	0.002	0.8 (0.3 – 1.3)
Day 1 to 7	97	115	2.54 (2.13)	1.55 (2.06)	0.001	0.9 (0.4 – 1.5)

* independent samples t-test

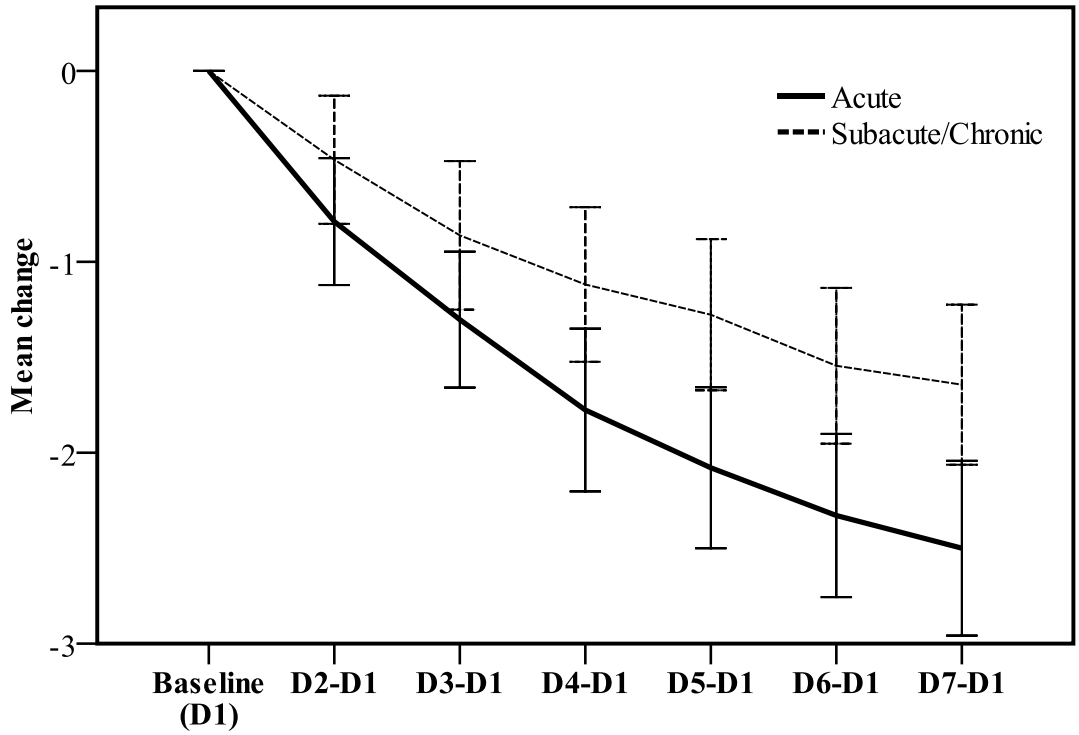


Figure 8.12 SMS pain daily change scores in acute and subacute/chronic patients
(error bars: 95% confidence intervals; D = day)

BQ change scores

The BQ sub-scale and total change scores at each of the outcome measurement points (4th visit, 3 months and 6 months) are shown in Tables 8.26 to 8.28. At each of the follow-up points, the change from baseline was consistently of a greater magnitude for the acute patients (Figure 8.13). Of the BQ sub-scales, change in pain, disability in activities of daily living, and disability in social activities were significantly different ($p < 0.001$) between the two subgroups at each outcome point, with the mean differences greatest for disability in activities of daily living and disability in social activities.

Table 8.26 Bournemouth Questionnaire sub-scale and total change scores at the 4th visit

BQ scores	Acute (n = 143)	Missing data	Sub-acute/ chronic (n = 173)	Missing data	* p-value	Mean difference (95% confidence interval)
Pain	4.0 (2.50)	74	2.7 (2.58)	53	< 0.001	1.3 (0.7 – 1.8)
Disability in activities of daily living	4.2 (3.15)	74	2.3 (2.82)	53	< 0.001	1.8 (1.2 – 2.5)
Disability in social activities	3.7 (3.29)	76	2.1 (3.16)	53	< 0.001	1.5 (0.8 – 2.2)
Anxiety	3.0 (2.95)	75	2.0 (2.81)	53	0.002	1.0 (0.3 – 1.6)
Depression	1.8 (2.74)	74	1.3 (2.54)	54	0.077	0.5 (-0.5 – 1.1)
Work fear-avoidance beliefs	2.9 (3.30)	74	2.2 (2.95)	54	0.051	0.6 (-0.004 – 1.3)
Locus of control	3.2 (2.82)	77	2.2 (2.96)	58	0.003	0.9 (0.3 – 1.6)
Total score	22.9 (15.49)	79	15.0 (14.96)	60	<0.001	7.6 (4.4 – 11.2)

Values are means (SD)
* independent samples t-test

Table 8.27 Bournemouth Questionnaire sub-scale and total change scores at 3 months

BQ scores	Acute (n = 85)	Missing data	Sub-acute/ chronic (n = 94)	Missing data	* p-value	Mean difference (95% confidence interval)
Pain	5.1 (2.98)	134	3.2 (2.90)	136	< 0.001	1.9 (1.0 – 2.7)
Disability in activities of daily living	5.6 (3.48)	134	2.9 (3.20)	136	< 0.001	2.6 (1.6 – 3.6)
Disability in social activities	5.2 (3.73)	135	2.7 (3.41)	136	< 0.001	2.5 (1.4 – 3.5)
Anxiety	3.3 (3.04)	135	2.5 (2.97)	136	0.097	0.7 (-0.1 – 1.6)
Depression	1.8 (3.12)	134	1.6 (2.69)	136	0.752	0.1 (-0.7 – 0.9)
Work fear-avoidance beliefs	3.9 (3.80)	135	2.3 (3.56)	138	0.004	1.6 (0.5 – 2.7)
Locus of control	3.9 (3.31)	135	2.9 (3.07)	137	0.030	1.0 (0.1 – 1.9)
Total score	28.6 (17.52)	137	15.4 (15.05)	139	< 0.001	10.7 (5.6 – 15.8)

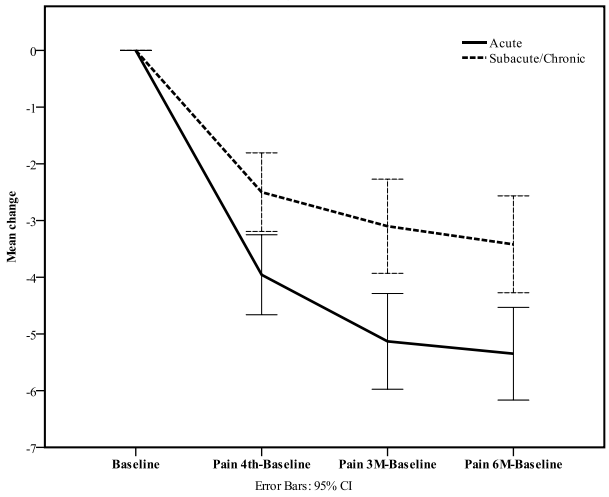
Values are means (SD)
* independent samples t-test

Table 8.28 Bournemouth Questionnaire sub-scale and total change scores at 6 months

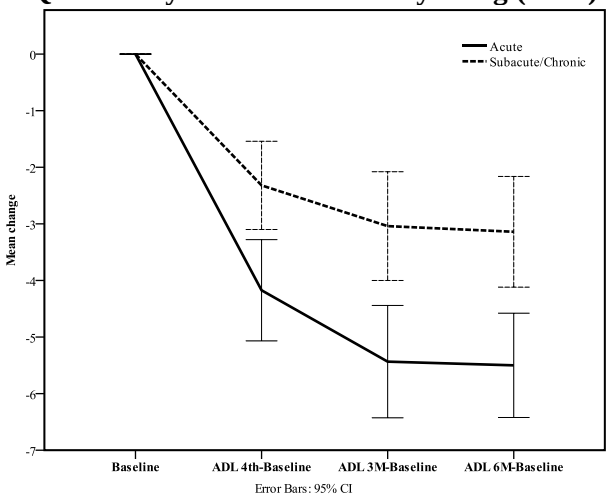
BQ scores	Acute (n = 73)	Missing data	Sub-acute/ chronic (n = 72)	Missing data	* p-value	Mean difference (95% confidence interval)
Pain	5.1 (2.90)	147	3.1 (3.19)	157	< 0.001	2.0 (1.0 – 3.0)
Disability in activities of daily living	5.3 (3.17)	147	2.9 (3.56)	157	< 0.001	2.3 (1.2 – 3.4)
Disability in social activities	5.2 (3.26)	147	2.4 (3.88)	157	< 0.001	2.8 (1.6 – 4.0)
Anxiety	3.5 (3.12)	147	2.0 (3.27)	158	0.005	1.4 (0.4 – 2.5)
Depression	2.2 (3.22)	147	1.2 (3.21)	157	0.044	1.0 (0.02 – 2.1)
Work fear-avoidance beliefs	4.3 (3.23)	149	2.6 (3.34)	158	0.002	1.6 (0.6 – 2.7)
Locus of control	3.9 (3.11)	147	2.6 (3.48)	158	0.020	1.2 (0.2 – 2.3)
Total score	30.2 (16.92)	149	16.3 (19.15)	160	< 0.001	13.8 (7.9 – 19.8)

Values are means (SD)
* independent samples t-test

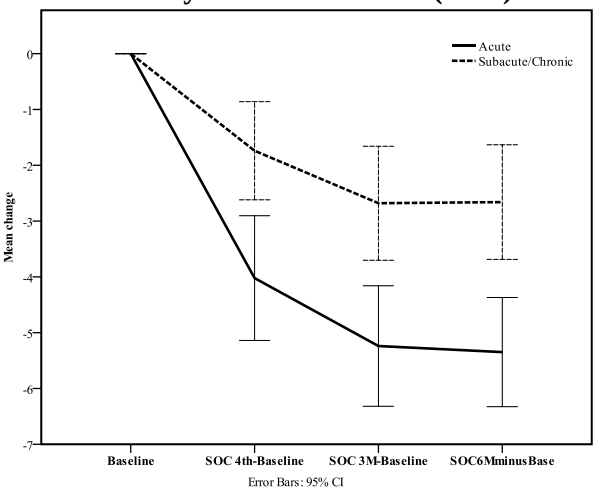
BQ Pain



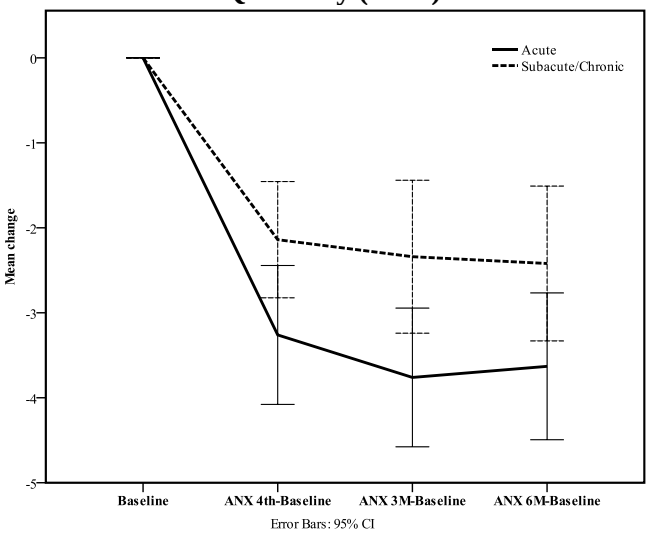
BQ Disability in activities of daily living (ADL)



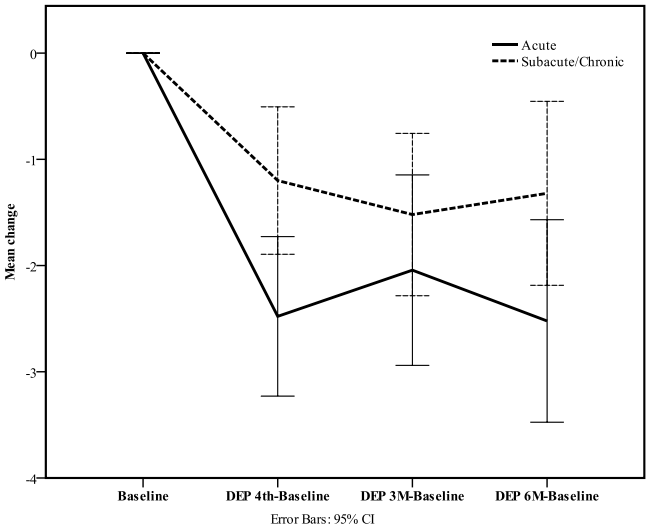
Disability in social activities (SOC)



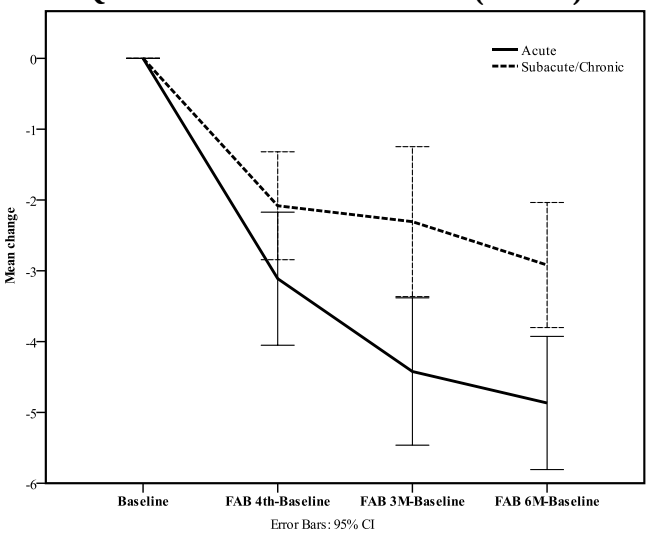
BQ Anxiety (ANX)



BQ Depression (DEP)



BQ Work fear-avoidance beliefs (WFAB)



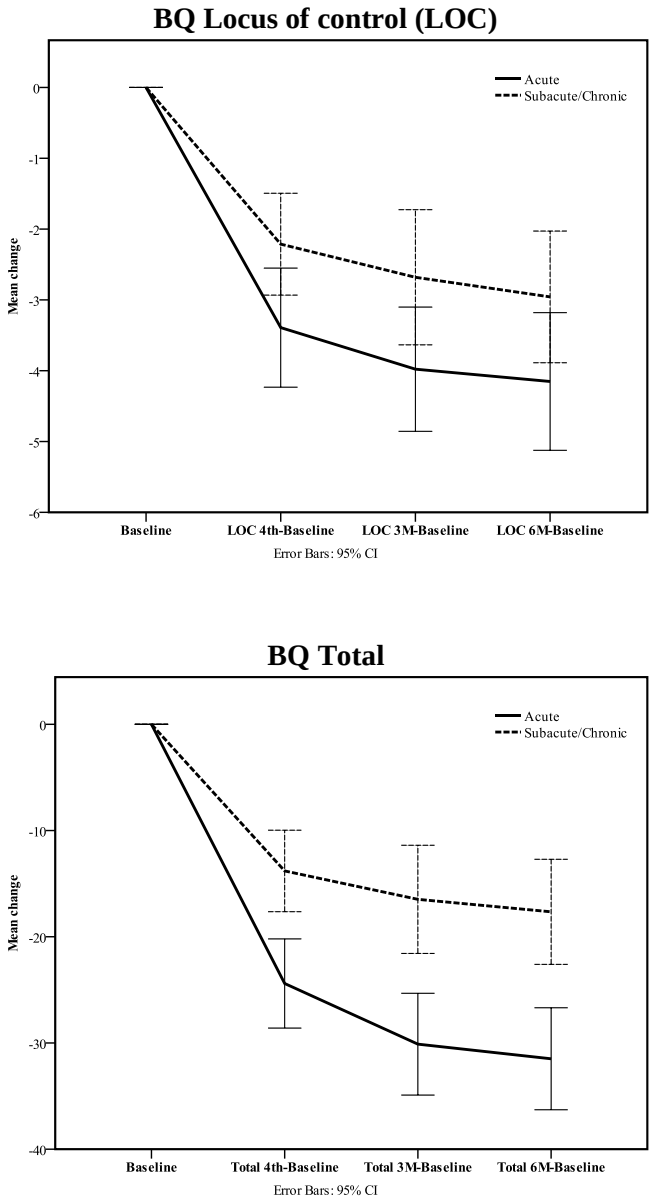


Figure 8.13 Bournemouth Questionnaire sub-scales and total change scores (mean values) at 4th visit, 3 months and 6 months in acute and subacute/chronic patients (error bars: 95% confidence intervals)

8.5 Predictors of outcome

Prior to conducting the analysis, several of the categorical baseline variables (potential predictors) were collapsed thereby reducing the number of categories for ease of interpretation and clinical relevance. Furthermore, potential baseline predictor variables recorded as continuous data were transformed in to categorical data at the mean or median values.

8.5.1 Univariate analysis

Logistic regression (univariate) analysis was performed for all baseline predictor variables and change score variables *versus* the outcome variable 'improved' derived from the dichotomised PGIC as previously described. Tables 8.29a and 8.29b summarise the baseline predictor variables that were significantly associated with the outcome 'improved' at follow-up on Day 1, 4th visit, 3 months and 6 months in acute and subacute/chronic patients. A summary of the significant change score predictor variables (BQ, SMS, and PGIC) is shown in Table 8.30a and 8.30b for the acute and subacute/chronic patients respectively.

Baseline predictor variables

Following univariate analysis of the baseline predictor variables with the outcome on Day 1, only a single variable (the patient's description of their LBP) was significantly associated with improvement in the acute patient group. For the subacute/chronic patients, increasing age and higher levels of interference with daily activities were associated with reduced odds of improvement on Day 1. Additionally, two work-related variables were significantly associated with the outcome in this cohort.

The number of baseline variables significantly associated with improvement increased in both subgroups at the 4th visit, 3 months and 6 months compared to Day 1. At each

of these follow-up points, a greater number of predictor variables were associated with improvement in the acute patients than the subacute/chronic group, as presented in Table 8.29a and 8.29b. The baseline variables significantly associated with improvement at each of the follow-up points for the acute and subacute/chronic patients were broadly dispersed between the domains of sociodemographic characteristics, psychosocial factors, work-related factors, clinical characteristics, and physical examination findings. However, variables reflecting aspects of the patient-practitioner relationship were significantly associated with improvement solely at the 4th visit in both duration subgroups (Table 8.29a and 8.29b).

Change score predictor variables

In the acute patients, a greater magnitude of change in the SMS pain scores from Day 1 to Days 2, 4 and 6 was significantly associated with improvement at the 4th visit. Similarly, the SMS pain change scores on Days 2, 4 and 5 were associated with increased odds of improvement at 3 months. In contrast, only the extent of change in pain from Day 1 to Day 5 was significantly associated with improvement at the 4th visit in the subacute/chronic patients. However, a greater change in the SMS pain score from Day 1 to Days 3, 4, 5 and 7 was associated with improvement at 3 months, resembling the acute patient group (Table 8.30a and 8.30b).

As shown in Table 8.30a and 8.30b, univariate analysis of the BQ (sub-scale and total) change scores and improvement shows that all sub-scales at the 4th visit with the exception of disability in social activities, anxiety and depression were associated with improvement at 3 months in acute patients. The change scores of these sub-scales at the 4th visit, with the addition of disability in social activities, were also associated with improvement at 6 months. Furthermore, a greater magnitude of change from baseline to 3 months in the BQ sub-scales of pain, disability in activities of daily living and social activities and locus of control was associated with increased odds of improvement at 6 months.

In the subacute/chronic cohort, change scores for the BQ sub-scales at the 4th visit revealed a greater emphasis on psychosocial factors as anxiety, depression and locus of control were significantly associated with improvement in addition to pain. At 3 months, a greater magnitude of change for all 7 of the BQ sub-scales was associated with increased odds of subacute/chronic patients reporting improvement at the 6-month follow-up.

Acute patients who were categorised as improved by the PGIC at the 4th visit were significantly more likely to report improvement at 3 months. Additionally, improvement at 3 months increased the odds of being improved at 6 months. For the subacute/chronic cohort, improvement at the 4th visit was positively associated with improvement both at 3 months and 6 months (Table 8.30a and 8.30b).

Table 8.29a Univariate logistic regression analysis: summary of the baseline predictor variables significantly associated with improvement (p < 0.1) at Day 1, 4th visit, 3 months, and 6 months in acute patients (n = 222)

Predictor variable		Day 1 (n = 112) OR (95% CI) p	4th visit (n = 146) OR (95% CI) p	3 months (n = 87) OR (95% CI) p	6 months (n =73) OR (95% CI) p
Age	Units of change = 1				1.1 (1.0 – 1.2) 0.042
Gender	Male vs. Female		2.2 (0.9 – 5.2) 0.065		
Education level	College/University vs. Secondary school				3.8 (0.8 – 16.7) 0.076
BMI	Overweight or Obese vs. Normal weight		2.7 (1.1 – 6.6) 0.026		
Health comparison	Same or worse vs. Better			3.6 (0.9 – 14.4) 0.069	
Current compensation claim	No vs. Yes			14.6 (1.2-176) 0.035	
In paid work	Yes vs. No				5.9 (1.1 – 31.0) 0.036
Work bending/twisting	No vs. Yes		2.2 (0.8 – 5.9) 0.093		
Work lifting/carrying	No vs. Yes		2.2 (0.9 – 5.6) 0.077		
Work preventing recovery	No vs. Yes				5.2 (0.7 – 35.8) 0.094
Employer support	No vs. Yes			6.0 (0.7 – 46.3) 0.089	
Troublesome	Extremely vs. Moderately/slightly			3.3 (0.8 – 13.3) 0.087	
Describe pain	Comes and goes for no reason vs. All the time	7.5 (0.8 – 69.0) 0.075			
Worst pain	Wake up in morning vs. Afternoon/evening/night		3.7 (1.0 – 14.2) 0.050		
Difficulty turning in bed	Yes vs. No			5.8 (1.5 – 21.8) 0.008	
Difficulty sleeping	Yes vs. No			6.9 (0.8 – 56.5) 0.071	
Difficulty with shoes/socks	Yes vs. No			3.6 (1.0 – 12.9) 0.042	
Difficulty getting up from sitting	Yes vs. No			5.8 (1.5 – 21.3) 0.008	10.1 (2.2 – 47.0) 0.003
Total Nordic questions	3 or greater vs. Less than 3		2.0 (0.8 – 4.7) 0.096	8.8 (2.1 – 36.0) 0.002	
Neck pain	No vs. Yes		2.2 (0.9 – 5.4) 0.083		

Table 8.29a (continued)

Predictor variable		Day 1 (n = 112) OR (95% CI) p	4th visit (n = 146) OR (95% CI) p	3 months (n = 87) OR (95% CI) p	6 months (n =73) OR (95% CI) p
Shoulder/arm pain	No vs. Yes			5.9 (1.5 – 23.3) 0.010	
Leg pain below the knee	No vs. Yes			4.7 (1.1 – 20.0) 0.032	
Leg pain pattern	On and off vs. Constant		5.3 (1.2 – 22.3) 0.021		
Widespread pain	No areas vs. 1 area			6.7 (0.7 – 58.4) 0.082	
	No area vs. 2 or more areas			9.2 (0.9 – 90.7) 0.057	
BQ pain	Units of change = 1			0.6 (0.5 – 0.8) 0.006	
BQ daily activities	Units of change = 1			0.7 (0.5 – 0.9) 0.009	
BQ social routine	Units of change = 1			0.7 (0.6 – 0.9) 0.027	
BQ work fear-avoidance	Units of change = 1			0.8 (0.6 – 0.9) 0.036	
BQ pain (median)	High pain vs. Low pain			3.6 (1.0 – 12.9) 0.042	
BQ daily activities (median)	High interference vs. Low interference			3.3 (0.9 – 11.7) 0.057	
BQ social routine (median)	High interference vs. Low interference			3.7 (1.0 – 13.2) 0.038	
Treated by this chiropractor before	No vs. Yes			3.3 (0.9 – 11.7) 0.057	5.5 (1.2 – 24.6) 0.025
Current recovery expectation (patient)	Full vs. Partial/not				5.9 (1.3 – 25.6) 0.018
LBP past 12 months	30 days or less constant or on/off vs. more than 30 days constant or on/off				8.5 (1.6 – 43.1) 0.010
Type of onset	Sudden vs. Gradual		2.4 (1.0 – 5.9) 0.040	7.3 (1.9 – 27.6) 0.003	3.6 (0.7 – 16.8) 0.095
Pain in flexion	Yes vs. No			3.2 (0.9 – 11.3) 0.067	6.8 (1.2 – 37.1) 0.026
Pain in extension	Yes vs. No				10.9 (1.2 – 94.9) 0.030
Pain on palpation	Yes vs. No			5.0 (1.3 – 19.1) 0.019	11.2 (2.2 – 56.4) 0.003
Expected recovery by chiropractor at 3 months	Full vs. Partial or not sue			4.0 (1.0 – 14.9) 0.038	4.2 (0.9 – 19.4) 0.062
Mental resilience	Units of change = 1		1.2 (1.0 – 1.5) 0.027		

Table 8.29a (continued)

Predictor variable		Day 1 (n = 112) OR (95% CI) p	4th visit (n = 146) OR (95% CI) p	3 months (n = 87) OR (95% CI) p	6 months (n =73) OR (95% CI) p
Mental resilience (median)	Robust vs. Fragile		2.4 (1.0 – 5.7) 0.038		
Enough time	Units of change = 1		1.2 (1.0 – 1.4) 0.003		
Chiropractor understands	Units of change = 1		1.1 (1.0 – 1.3) 0.024		
Goals	Units of change = 1		1.1 (0.9 – 1.4) 0.056		
Chiropractor understands (mean)	Agree vs. Disagree		2.9 (1.0 – 7.8) 0.033		
Goals (mean)	Agree vs. Disagree		4.7 (1.6 – 13.7) 0.004		

OR = odds ratio; CI = confidence interval; p = p-value; vs. = *versus*

Table 8.29b Univariate logistic regression analysis: summary of the baseline predictor variables significantly associated with improvement (p < 0.1) at Day 1, 4th visit, 3 months, and 6 months in subacute/chronic patients (n = 230)

Predictor variable		Day 1 (n = 126) OR (95% CI) p	4th visit (n = 175) OR (95% CI) p	3 months (n = 95) OR (95% CI) p	6 months (n =73) OR (95% CI) p
Age	Units of change = 1	0.8 (0.8 – 1.0) 0.054			
Physical activity	Most of the time vs. Some of the time/almost never		1.9 (1.0 – 3.7) 0.050		3.1 (1.0 – 9.5) 0.042
Stress effect	Sometimes/rarely vs. Constantly/mostly		1.9 (0.9 – 3.7) 0.066		
In paid work	No vs. Yes	7.5 (1.3 – 40.8) 0.020			
Work bending/twisting	Yes vs. No			2.4 (0.9 – 6.6) 0.076	
Work driving	No vs. Yes				3.4 (0.9 – 12.1) 0.059
Job satisfaction	Dissatisfied vs. Satisfied	4.2 (0.7 – 22.2) 0.090			
Work preventing recovery	Yes vs. No			3.2 (0.8 – 12.4) 0.088	
Difficulty socks/shoes	No vs. Yes				3.2 (1.1 – 9.4) 0.027
Widespread pain	No areas vs. 2 or more areas		2.3 (1.0 – 5.2) 0.049	3.5 (0.9 – 12.8) 0.054	5.5 (1.0 – 28.6) 0.043
Current recovery expectation (patient)	Full vs. Partial/not		1.7 (0.9 – 3.1) 0.095		2.9 (1.0 – 8.5) 0.042
First time LBP	Never before vs. More than 5 years ago			6.1 (0.7 – 51.7) 0.093	
LBP days past 12 months	30 days or less constant or on/ off vs. More than 30 days constant or on/off			3.7 (1.3 – 10.5) 0.014	4.5 (1.1 – 17.7) 0.029
BQ daily activities	Units of change = 1	0.6 (0.4 – 0.9) 0.028			
BQ daily activities (median)	High interference vs. Low interference	9.3 (1.0 – 85.2) 0.042			
Type of onset	Sudden vs. Gradual		1.7 (0.9 – 3.4) 0.097		

Table 8.29b (continued)

Predictor variable		Day 1 (n = 126) OR (95% CI) p	4th visit (n = 175) OR (95% CI) p	3 months (n = 95) OR (95% CI) p	6 months (n =73) OR (95% CI) p
LBP on one side	Yes vs. No			3.0 (1.2 – 7.4) 0.015	3.5 (1.2 – 10.5) 0.020
Pain in flexion	Yes vs. No			2.4 (0.9 – 5.6) 0.054	
Pain lingers after examination				2.4 (0.9 – 6.5) 0.075	
Immediate improvement after treatment	No vs. Yes			2.5 (0.8 – 7.1) 0.082	
Expected recovery by chiropractor at 3 months	Full vs. Partial/not sure			2.9 (1.1 – 7.4) 0.023	4.0 (1.2 – 12.8) 0.020
Physical constitution	Units of change = 1				0.7 (0.5 – 1.0) 0.091
Mental resilience (median)	Fragile vs. Robust			2.5 (1.0 – 6.3) 0.042	
Enough time	Units of change = 1		1.1 (1.0 – 1.2) 0.043		
Goals (mean)	Agree vs. Disagree		2.0 (0.9 – 4.5) 0.063		

OR = odds ratio; CI = confidence interval; p = p-value; vs. = *versus*

Table 8.30a Univariate logistic regression analysis: summary of the text message (SMS), Bournemouth Questionnaire (BQ) change scores and Patient's Global Impression of Change (PGIC) significantly associated with improvement ($p < 0.1$) at 4th visit, 3 months, and 6 months in acute patients (n = 222)

Change scores		Outcome point	Odds Ratio	95% Confidence Interval	p value (< 0.1)
SMS Pain (Day 1 to Day 2)	Units of change = 1	4th visit	1.6	1.0 – 2.5	0.037
SMS Pain (Day 1 to Day 4)	Units of change = 1	4th visit	1.4	1.0 – 2.1	0.038
SMS Pain (Day 1 to Day 6)	Units of change = 1	4th visit	1.4	1.0 – 2.0	0.038
SMS Pain (Day 1 to Day 2)	Units of change = 1	3 months	1.8	0.9 – 3.3	0.052
SMS Pain (Day 1 to Day 4)	Units of change = 1	3 months	1.5	0.9 – 2.4	0.076
SMS Pain (Day 1 to Day 5)	Units of change = 1	3 months	1.5	0.9 – 2.5	0.094
BQ PAIN (Baseline to 4th)	Units of change = 1	3 months	1.4	1.1 – 1.9	0.004
BQ ADL (Baseline to 4th)	Units of change = 1	3 months	1.3	1.0 – 1.6	0.007
BQ WFAB (Baseline to 4th)	Units of change = 1	3 months	1.2	1.0 – 1.4	0.040
BQ LOC (Baseline to 4th)	Units of change = 1	3 months	1.3	1.0 – 1.6	0.018
BQ PAIN (Baseline to 4th)	Units of change = 1	6 months	1.8	1.1 – 2.8	0.010
BQ ADL (Baseline to 4th)	Units of change = 1	6 months	2.3	1.2 – 4.3	0.010
BQ SOC (Baseline to 4th)	Units of change = 1	6 months	1.3	1.0 – 1.7	0.029
BQ WFAB (Baseline to 4th)	Units of change = 1	6 months	1.4	1.0 – 2.0	0.028
BQ LOC (Baseline to 4th)	Units of change = 1	6 months	1.4	1.0 – 1.9	0.037
BQ Total (Baseline to 4th)	Units of change = 1	6 months	0.9	0.9 – 1.0	0.072
BQ PAIN (Baseline to 3 months)	Units of change = 1	6 months	1.4	1.0 – 1.9	0.019
BQ ADL (Baseline to 3 months)	Units of change = 1	6 months	1.3	1.0 – 1.8	0.021
BQ SOC (Baseline to 3 months)	Units of change = 1	6 months	1.2	1.0 – 1.6	0.029
BQ LOC (Baseline to 3 months)	Units of change = 1	6 months	1.7	1.1 – 2.7	0.011
BQ Total (Baseline to 3 months)	Units of change = 1	6 months	0.8	0.7 – 0.9	0.009
Improved at 4th visit		3 months	5.5	1.4 – 21.1	0.012
Improved at 3 months		6 months	14.3	2.3 – 87.9	0.004

Table 8.30b Univariate logistic regression analysis: summary of the text message (SMS), Bournemouth Questionnaire (BQ) change scores and Patient's Global Impression of Change (PGIC) significantly associated with improvement (p < 0.1) at 4th visit, 3 months, and 6 months in subacute/chronic patients (n = 230)

Change scores		Outcome point	Odds Ratio	95% Confidence Interval	p value (< 0.1)
SMS Pain (Day 1 to Day 5)	Units of change = 1	4th visit	1.2	0.9 – 1.5	0.078
SMS Pain (Day 1 to Day 3)	Units of change = 1	3 months	1.4	1.0 – 2.0	0.022
SMS Pain (Day 1 to Day 4)	Units of change = 1	3 months	1.2	0.9 – 1.7	0.080
SMS Pain (Day 1 to Day 5)	Units of change = 1	3 months	1.4	1.0 – 2.0	0.012
SMS Pain (Day 1 to Day 7)	Units of change = 1	3 months	1.3	1.0 – 1.8	0.035
BQ PAIN (Baseline to 4th)	Units of change = 1	3 months	1.1	0.9 – 1.4	0.072
BQ ADL (Baseline to 4th)	Units of change = 1	3 months	1.2	1.0 – 1.4	0.022
BQ DEP (Baseline to 4th)	Units of change = 1	3 months	1.2	1.0 – 1.6	0.017
BQ LOC (Baseline to 4th)	Units of change = 1	3 months	1.1	0.9 – 1.3	0.086
BQ PAIN (Baseline to 3 months)	Units of change = 1	6 months	1.4	1.1 – 1.9	0.004
BQ ADL (Baseline to 3 months)	Units of change = 1	6 months	1.3	1.0 – 1.7	0.006
BQ SOC (Baseline to 3 months)	Units of change = 1	6 months	1.2	1.0 – 1.4	0.046
BQ ANX (Baseline to 3 months)	Units of change = 1	6 months	1.2	1.0 – 1.5	0.048
BQ DEP (Baseline to 3 months)	Units of change = 1	6 months	1.4	1.0 – 1.9	0.033
BQ WFAB (Baseline to 3 months)	Units of change = 1	6 months	1.2	0.9 – 1.4	0.063
BQ LOC (Baseline to 3 months)	Units of change = 1	6 months	1.3	1.0 – 1.6	0.015
BQ Total (Baseline to 3 months)	Units of change = 1	6 months	0.8	0.8 – 0.9	0.001
Improved at 4th visit		3 months	3.8	1.4 – 10.1	0.007
Improved at 4th visit		6 months	3.2	1.0 – 9.9	0.040

8.5.2 Multivariate analysis

Predictive models for improvement (dichotomised PGIC) were constructed for the acute and subacute/chronic patient subgroups at Day 1, 4th visit, 3 months and 6 months. Models for baseline (Tables 8.31a to 8.31c), SMS change score (Tables 8.32a to 8.32b) and BQ change score (Tables 8.33a to 8.33c) predictor variables were constructed separately and then in combination (Tables 8.4a to 8.34c).

At each of the outcome measurement points for the acute and subacute/chronic groups the number of patients included in the multivariate analysis (with the exception of the baseline predictor variable models in acute patients at the 4th visit and 6 months) did not equate to the number of patients who responded at each follow-up. This was due to case-wise deletion by the statistical analysis software programme, as only complete cases were eligible for inclusion in the multivariate logistic regression analysis. The number of patients included in the multivariate analysis at each follow-up is indicated in the respective tables.

Improvement on Day 1

In the multivariate analysis, for either the acute or subacute/chronic subgroups, none of the baseline or change score predictor variables (as separate or combined models) were independently associated with improvement on Day 1.

Improvement at the 4th visit

Acute patients

In the final model for the baseline predictors in the acute patients, experiencing a sudden onset of LBP was independently associated with improvement. Furthermore, a patient not having sufficient time with the chiropractor was independently associated with reduced odds of improvement (Table 8.31a). The area under the ROC curve (AUC) was 0.28, indicating that this model was poor in discriminating between those patients who improved and those who did not.

In the model for the SMS pain change scores at the 4th visit in the acute patients, a degree of change in pain in the first 5 days following the initial consultation (from Day 1 to Day 6) was independently associated with improvement (Table 8.31a). Again, the model had a poor discriminative ability (AUC 0.30). Furthermore, when combined with the baseline predictor variables, the SMS pain change from Day 1 to Day 6 was again independently associated with the outcome although the discriminative ability of the final model (AUC 0.26) remained poor (Table 8.34a).

Subacute/chronic patients

As shown in Table 8.31a, being physically active most of the time was independently associated with improvement at the 4th visit in the multivariate analysis of the baseline predictor variables. Additionally, as with the acute patients, not having sufficient time with the chiropractor was independently associated with reduced odds of improvement. The model approached acceptable discrimination between those patients who improved and those who did not (AUC 0.68).

In the univariate analysis, only one SMS pain change score variable remained significantly associated with improvement at the 4th visit (Table 8.30b). However, as the level of statistical significance (p-value) exceeded 0.05, the variable was not included in the multivariate analysis. Consequently, for the subacute/chronic cohort, only baseline predictor variables comprised the final predictive model at the 4th visit (Table 8.31a).

Improvement at 3 months

Acute patients

In the multivariate model of the baseline prognostic variables, difficulty experienced with turning in bed was the only variable that was independently associated with improvement at 3 months in the acute patients (Table 8.31b).

At 3 months, in the predictive model for the SMS change scores, a greater magnitude of change in pain from Day 1 to Day 2 was independently associated with increased odds of improvement in acute patients (Table 8.32b). Furthermore, this model had acceptable discrimination (AUC 0.81). As shown in Table 8.33a for the BQ change score model, an increased magnitude of change in the pain sub-scale from baseline to the 4th visit was independently associated with improvement at 3 months. Again, this model demonstrated acceptable discriminative ability (AUC 0.74).

In the final model combining the baseline predictors, SMS and BQ change score variables independently associated with improvement, only the baseline variable 'difficulty turning in bed' remained independently associated with outcome at 3 months; however the model demonstrated no discriminative ability (Table 8.34b).

Subacute/chronic patients

As shown in Table 8.31b, pain experienced by the patient during flexion of their low back during the physical examination at the 1st visit was independently associated with increased odds of improvement at 3 months. This model had good discriminative ability (AUC 0.82) and correctly identified approximately equal numbers of improved and non-improved patients (66.7% and 61.9% respectively).

A greater amount of change in the SMS pain score from Day 1 to Day 5 was independently associated with improvement in the subacute/chronic patients at 3 months (Table 8.32b). Furthermore, the discriminative ability (AUC 0.72) was acceptable. For the BQ, a greater amount of change in the depression sub-scale (from baseline to the 4th visit) was independently associated with increased odds of improvement at 3 months (Table 8.33a). Moreover, the AUC (0.69) of the BQ change score model resembled the SMS model, indicating acceptable discriminative ability.

Once the significant baseline predictors, SMS and BQ change score variables were combined, the only variable to remain independently associated with the outcome was the SMS pain change score from Day 1 to Day 5 (Table 8.34b). However, this final model was poor at discriminating between improved and non-improved patients (AUC 0.25).

Improvement at 6 months

Acute patients

In the multivariate analysis of the significant baseline variables, difficulty experienced with getting up from sitting, and if the patient had not previously received care from the treating chiropractor were each independently associated with improvement at 6 months. However, as presented in Table 8.31c, the model had poor discriminative ability (AUC 0.12).

There were no SMS variables that were independently associated with improvement at 6 months in the acute patients. However, of the BQ sub-scales, a greater magnitude of change in disability in activities of daily living from baseline to the 4th visit was independently associated with increased odds of improvement at 6 months (Table 8.33b). Furthermore, increased change in the locus of control sub-scale score between baseline and 3 months was independently associated with improvement at 6 months in acute patients (Table 8.33c). Nevertheless, neither of these models had the ability to discern between improved and non-improved patients (AUC 0.09 and 0.19).

In the final combined multivariate model at 6 months, change in the BQ disability of activities of daily living sub-scale score from baseline to the 4th visit remained independently associated with improvement (Table 8.34c). The AUC for this model was 0.07 demonstrating no discriminative ability whatsoever.

Subacute/chronic patients

At 6 months, being physically active most of the time, experiencing difficulty putting on shoes or socks, and the expectation of the patient making a full recovery by the chiropractor were all independently associated with improvement in the subacute/chronic patient cohort (Table 8.31c). This predictive model demonstrated good discriminative ability (AUC 0.87).

Similar to the acute patients, there were no SMS pain change score variables that were independently associated with the outcome in the subacute/chronic group at 6 months. However, a greater amount of change in the BQ pain sub-scale score from baseline to 3 months was associated with increased odds of improvement at 6 months (Table 8.33c). The AUC of this model was 0.81, again indicating good discriminative ability.

Table 8.34c shows the combined predictive model for the subacute/chronic patients at 6 months. Improvement reported at the 4th visit was independently associated with improvement at 6 months, as was difficulty experienced with putting on shoes or socks. However, this final model was poor in discriminating between improved and non-improved patients (AUC 0.26).

Table 8.31a Multivariate logistic regression analysis of prognostic variables at baseline for improvement at the 4th visit

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 146				
Type of onset (*sudden vs. gradual*)	2.7	1.1 – 6.9	0.028	98.3%; 11.1%;
Not enough time with chiropractor (*unit of change = 1*)	0.7	0.6 – 0.9	0.002	82.2%; 0.28 (0.17 – 0.39)
Subacute/chronic n = 152				
Physical activity (*most of the time vs. some of the time/almost never*)	2.1	1.0 – 4.5	0.035	83.5%; 37.7%; 65.1%; 0.68 (0.59 – 0.76)
Not enough time with chiropractor (*unit of change = 1*)	0.8	0.7 – 0.9	0.033	

vs. = *versus*; OR = odds ratio; CI = confidence interval

Table 8.31b Multivariate logistic regression analysis of prognostic variables at baseline for improvement at 3 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 43				
Difficulty turning in bed (*yes vs. no)*	15.0	1.4 – 153.5	0.022	100%; 0%; 88.4%; **
Subacute/chronic n = 54				
Pain in flexion (*yes vs. no*)	3.2	1.0 – 10.1	0.043	66.7%; 61.9%; 64.8%; 0.82 (0.71 – 0.93)

vs. = *versus*; OR = odds ratio; CI = confidence interval
** area under ROC curve not calculated

Table 8.31c Multivariate logistic regression analysis of prognostic variables at baseline for improvement at 6 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 73				
Treatment from this chiropractor before (*no vs. yes*)	18.2	1.6 – 142.1	0.017	98.4%; 22.2%; 89.0%;
Difficulty getting up from sitting *(yes vs. no)*	27.3	2.8 – 261.7	0.004	0.12 (0.03 – 0.21)
Subacute/chronic n = 55				
Physical activity *(most of the time vs. some of the time/almost never)*	7.6	1.2 – 46.0	0.026	72.4%;77.8%; 74.5%; 0.87 (0.76 – 0.97)
Difficulty with socks or shoes *(no vs. yes*)	5.2	1.2 – 22.7	0.026	
Recovery expectation by chiropractor *(full vs. partial/not sure)*	10.4	1.6 – 65.9	0.012	

vs. = *versus*; OR = odds ratio; CI = confidence interval

Table 8.32a Multivariate logistic regression analysis of SMS pain change scores for improvement at the 4th visit

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 66				
SMS pain change Day 1 to Day 6 (*unit of change = 1*)	1.4	1.0 – 2.1	0.047	100%; 7.7%; 81.8%; 0.30 (0.10 – 0.49)

OR = odds ratio; CI = confidence interval

Table 8.32b Multivariate logistic regression analysis of SMS pain change scores for improvement at 3 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 44				
SMS pain change Day 1 to Day 2 (*unit of change = 1*)	2.0	1.0 – 3.9	0.041	97.4%; 16.7%; 86.4%; 0.81 (0.66 – 0.95)
Subacute/chronic n = 56				
SMS pain change Day 1 to Day 5 (*unit of change = 1*)	1.4	1.0 – 1.9	0.018	91.9%; 26.3%; 69.6%; 0.72 (0.58 – 0.86)

OR = odds ratio; CI = confidence interval

Table 8.33a Multivariate logistic regression analysis of BQ change scores (sub-scales) from baseline to the 4th visit for improvement at 3 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 70				
BQ Pain (*unit of change = 1*)	1.4	1.1 – 1.9	0.004	98.3%; 16.7%; 84.3%; 0.74 (0.57 – 0.91)
Subacute/chronic n = 82				
BQ Depression (*unit of change = 1*)	1.2	1.0 – 1.5	0.019	92.5%;10.3%; 63.4%; 0.69 (0.57 – 0.80)

OR = odds ratio; CI = confidence interval

Table 8.33b Multivariate logistic regression analysis of BQ change scores (sub-scales) from baseline to the 4th visit for improvement at 6 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 56				
BQ Disability in activities of daily living (*unit of change = 1*)	2.3	1.2 – 4.3	0.010	95.9%; 57.1%; 91.1%; 0.09 (0.00 – 0.23)

OR = odds ratio; CI = confidence interval

Table 8.33c Multivariate logistic regression analysis of BQ change scores (sub-scales) from baseline to 3 months for improvement at 6 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 54				
BQ Locus of control (*unit of change = 1*)	1.7	1.1 – 2.7	0.011	100%; 28.6%; 90.7%; 0.19 (0.04 – 0.34)
Subacute/chronic n = 52				
BQ Pain (*unit of change = 1)*	1.4	1.1 – 1.9	0.005	94.4%; 37.5%; 76.9%; 0.81 (0.66 – 0.95)

OR = odds ratio; CI = confidence interval

Table 8.34a Multivariate logistic regression analysis of prognostic variables at baseline and change scores for improvement at the 4th visit

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 74				
SMS pain change Day 1 to Day 6 *(unit of change = 1)*	1.4	1.0 – 2.0	0.038	100%; 6.7%; 81.1%; 0.26 (0.10 – 0.43)
Subacute/chronic n = 152				
Physical activity (*most of the time* vs. *some of the time/almost never*)	2.1	1.0 – 4.5	0.035	83.5%; 37.7%; 65.1%; 0.68 (0.59 – 0.76)
Not enough time with chiropractor (*unit of change = 1*)	0.8	0.7 – 0.9	0.033	

vs. = *versus*; OR = odds ratio; CI = confidence interval

Table 8.34b Multivariate logistic regression analysis of prognostic variables at baseline and change scores for improvement at 3 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 42				
Difficulty turning in bed (*yes vs. no)*	10.0	1.5 – 62.7	0.014	100%; 0%; 83.3%; **
Subacute/chronic n = 53				
SMS pain change Day 1 to Day 5 *(unit of change = 1)*	1.4	1.0 – 1.9	0.020	94.4%; 23.5%; 71.7%; 0.25 (0.11 – 0.39)

vs. = *versus*; OR = odds ratio; CI = confidence interval
** area under ROC curve not calculated

Table 8.34c Multivariate logistic regression analysis of prognostic variables at baseline and change scores for improvement at 6 months

	OR	95% CI	p-value	Sensitivity; Specificity; Percentage correctly predicted; Area under ROC curve (95% CI)
Acute n = 46				
BQ 4th Disability in activities of daily living (*unit of change = 1*)	2.4	1.2 – 4.9	0.011	97.7%; 57.1%; 91.3%; 0.07 (0.00 – 0.18)
Subacute/chronic n = 47				
PGIC 4th *(improved vs. not improved)*	5.2	1.4 – 19.5	0.013	95.9%; 33.3%; 79.1%; 0.26 (0.13 – 0.40)
Difficulty with socks or shoes *(no vs. yes)*	5.6	1.5 – 21.1	0.010	

vs. = *versus*; OR = odds ratio; CI = confidence interval

Chapter 9: Discussion

9.1 Introduction

The main purpose of this study was to identify prognostic factors that predict global improvement over a period of 6 months in LBP patients receiving chiropractic treatment. Heterogeneous, albeit few, baseline variables from domains including clinical characteristics, disability and psychological factors, clinical examination findings, and the patient-practitioner relationship were found to predict outcome at any follow-up point. Changes in pain in the immediate short term predicted improvement in both acute and subacute/chronic patients; however, this did not extend beyond the follow-up at 3 months in either duration subgroup. Short term changes in the BQ had some utility in identifying patients who improved, particularly in the pain and psychological domains of the BQ. As with other similar studies, very early change has been shown to be a significant prognostic factor in this study, particularly in acute patients.

This chapter is structured in such a way as to introduce aspects of the clinical course of LBP followed by a discussion of the prognostic models constructed at a number of follow-up points, and concludes with the strengths and limitations of the study and considerations for future research.

9.2 Sample characteristics

9.2.1 Chiropractors

The demographic and practice patterns of the chiropractors that returned data resembled those of the non-participant practitioners. Although it was not possible to obtain comparative data for the underlying population (the entire practising BCA membership in 2009), the chiropractors recruited to this study compare well with the most recent survey data of the profession conducted in the UK [157-159]. Although a slightly higher proportion, as compared to the findings from the GCC survey [158], reported working

alongside other chiropractors, the GCC survey included chiropractors affiliated to all the professional associations not solely the BCA, albeit this association represents the largest membership. However, based on recent surveys, the sample of chiropractors in this study was considered largely representative of the chiropractic profession in the UK.

9.2.2 Patients

The majority of the patients (both the participants and those who declined to participate) were between 30 and 49 years of age and almost half were female, closely resembling the age group and gender distribution of patients that most frequently consult chiropractors in the UK [157, 158]. Of the participants, age and gender were comparable between the acute and subacute/chronic subgroups at baseline. The mean number of days between the 1st and the 4th visit were almost equal between the acute and subacute/chronic subgroups and although the majority of patients received their 4th treatment within 2 weeks of their initial consultation, this was only by a marginally higher proportion of acute patients. However, the subgroups in this study were defined by the duration of LBP at the initial consultation as either less or greater than 2 weeks (acute and subacute/chronic cohorts, respectively). Consequently, subacute and chronic LBP patients were combined in a potentially heterogeneous duration subgroup.

9.3 Clinical course

The clinical course is differentiated from the natural history by the presence of a treatment intervention and as such, the LBP patients in this study were receiving chiropractic care. Overall, the clinical course of LBP observed in this study was in accordance with that in the literature with the most rapid improvement occurring in the short term [15, 160]. A systematic review of prognosis in acute LBP patients conducted by Pengel *et al.* [15] reported a 58% pooled mean reduction in initial levels of pain within the first month. This largely resembles the magnitude of pain reduction in this study presented here, as by the 4th visit, the mean pain scores (as recorded using the BQ) had decreased by 63% in the acute patients. This decrease in pain was of a lesser magnitude

for the subacute/chronic patients (50%), however, acute LBP patients typically present with higher LBP intensity than subacute/chronic patients, but they nevertheless improve more rapidly, a pattern that is consistent with several studies using the BQ [140, 161].

Indeed, in a recent UK study of acute and persistent LBP patients undergoing chiropractic care which used the BQ as a primary measure [119], the authors reported that each of the mean BQ sub-scale scores at baseline was higher for the acute patients, with significantly higher levels of pain, disability, anxiety, and work fear-avoidance beliefs reported. In the study presented here, although all mean BQ sub-scale scores in both duration subgroups decreased by the greatest magnitude in the short term (by the 4th visit), this was by a greater extent in the acute cohort, largely confirming the typical early course pattern of LBP consistently reported in other prospective studies of LBP patients receiving chiropractic treatment [109, 110, 114, 140, 161].

A potential limitation of many longitudinal studies is found in the small number of outcome measurement points over time. However, increasing the resolution by the addition of more outcome points within the same study duration may provide greater insight into patterns in the clinical course of LBP, particularly in the very short term. In this respect, recent prospective studies of chiropractic LBP patients conducted in Denmark and Sweden have utilised text-messaging to collect frequent follow-up data on a weekly basis over a period of 18 weeks and 6 months respectively. Rapid improvement early in the clinical course of LBP was reported by the authors [17, 143]. In the study presented here, a similar pattern emerged from data collected on a daily basis during the first week following the initial chiropractic consultation, where the mean pain scores decreased on each successive day in both duration subgroups. Indeed, the mean pain scores had dropped by the greatest magnitude by the end of the first week, decreasing by almost 3 and 2 points (on an 11-point NRS) in the acute and subacute/chronic patients respectively. Although this did not reach the threshold of minimal clinically important change [140] for the BQ pain sub-scale (3.5 in acute and 2.5 in subacute/chronic LBP patients), the mean difference in SMS pain score from Day 1 to each of the successive days was statistically significant in both duration subgroups

except between Day 1 and 2 in the subacute/chronic patients. This would suggest a more rapid change in pain immediately following the 1st visit in the acute patients in this study whereas this effect is slightly delayed in the subacute/chronic patients. Only minor decreases in the pain scores occurred thereafter with the scores at the 4th visit resembling those at end of the first week. This provides additional support, at a greater resolution, that the most rapid change in pain for LBP patients undergoing treatment may occur very early in the clinical course, albeit more so in acute patients.

On the day following the 1st visit the vast majority of patients in both duration subgroups were categorised as 'not improved' on the PGIC, suggesting that the first day following the initial consultation may be too early to detect meaningful improvement. As previously described, it was not feasible to analyse the PGIC data for days 2 to 7 in the first week. The phrasing of this PGIC text message question had mistakenly asked patients to rate how their LBP complaint had changed over the past 24 h whereas it should instead have directed the patient towards assessing their global change since the onset of the current treatment course. In this study presented here, there was a statistically significant correlation between pain and global improvement at each outcome measurement point in both duration subgroups, indicating that the pain and PGIC data followed a similar course data in this study. From the first follow-up on Day 1, there was a positive correlation between these variables. This is perhaps as expected, as with a greater magnitude of change in pain from baseline to the follow-up point so the corresponding PGIC score would be of a higher value denoting global improvement.

By the 4th visit, the majority of patients in both duration subgroups were categorised as improved and thereafter both the BQ and PGIC scores remained fairly static from 3 months to the final follow-up at 6 months. This prognostic pattern is supported by other prospective studies of LBP patients in primary care that have reported little if any development in improvement beyond 6 months [15, 112, 162]. Furthermore, LBP relapses are common [16, 114, 163] and as recently reported by Kongsted and Leboeuf-Yde [17,] even among LBP patients who experienced improvement in the early clinical course, the majority did not ultimately achieve a full recovery.

9.4 Predictors of outcome

9.4.1 Baseline variables

A greater duration of pain consistently emerges as a predictor of poor outcome of LBP and musculoskeletal pain in general in prognostic studies in primary care [108]. As the duration of the current episode was significantly associated with the outcome at each follow-up point in this study, the cohort of LBP patients was subgrouped according to duration and therefore this variable was not entered as potential predictor of outcome in the logistic regression analysis.

Previous duration of LBP has been shown to predict outcome [111, 164]. Furthermore, a clinically relevant cut-point of 30 days over the previous 12 months has been established from previous studies [111, 165]. In this present study, univariate logistic regression analysis of acute LBP patients that reported less than 30 days of LBP in the previous year had significantly higher odds of improvement at 6 months. This prognostic factor was also significantly associated with improvement in the subacute/chronic patients at the 3 and 6 month follow-up. These findings are supported by a recent Swedish study of LBP patients undergoing chiropractic care [143], as previous duration of LBP was shown to be a significant predictor of bothersome pain days at 6 months in those patients who had experienced 30 days or more of bothersome pain during the past year compared with those patients that reported a shorter previous duration of LBP.

Although previous duration of LBP as a prognostic factor was retained in the predictive models of earlier Swedish and Finnish studies of chiropractic patients, in that patients with at least 30 days of LBP over the previous year were not good candidates for recovery in the short term (at the 4th visit) [111, 115], unlike these Scandinavian studies, this variable was not retained in the final predictive models in this present study. However, several baseline variables that were not measured in previous similar studies, for example domains of the patient-practitioner relationship, had a comparatively stronger association with the outcome in the study presented here. Consequently, this may

explain why several variables seen in the predictive models of outcome in other studies, such as previous duration of LBP and leg pain (although significantly associated with improvement in the medium term in acute patients) were not retained in the prognostic models in this study.

The predictive models in this study for improvement in the short term (4th visit) comprised 2 variables for both the acute and subacute/chronic subgroups. A sudden onset of the current LBP episode predicted improvement in acute patients, whereas those patients who were physically active most of the time were more likely to report improvement in the subacute/chronic group. In addition to these variables, whether the patient felt the chiropractor had spent enough time with them during the initial consultation was retained in the predictive model at the 4th visit for both duration subgroups. This variable forms part of the patient-practitioner relationship but only appeared to influence short term outcome in this study. This may be because beyond the short term patients that are not improving perhaps 'lose faith' in the treatment and/or the practitioner, and hence the influence of this bond with the practitioner is attenuated. However, further study is needed to corroborate or otherwise this conjecture.

The patient-practitioner relationship, or therapeutic alliance, evolved out of psychotherapy and has been shown to be a significant predictor of outcome in this therapeutic approach [166]. Recent studies have emerged that demonstrate the important influence of this relationship on treatment outcomes in low back and neck pain patients in primary care [167], and in patients undergoing physical rehabilitation [168]. In the study presented here, although each domain of the patient-practitioner relationship (agreement on treatment goals and interventions, and the affective bond between patient and practitioner [169]) was significantly associated with the outcome, only the variable 'enough time' remained in the final prognostic models in the short term (4th visit) for both duration subgroups. A patient's perception of having enough time with the practitioner during the consultation has been linked with satisfaction with care, and this is in turn a component of the patient-practitioner relationship [170, 171]. Interestingly, in a

prognostic study of Norwegian chiropractic LBP patients [112], satisfaction with treatment was associated with outcome only in the short term (4th visit).

Of the baseline prognostic factors associated with improvement in the medium and longer term (at 3 and 6 months), in contrast with the final models at the 4th visit, there was considerable heterogeneity in variables between the duration subgroups. The models at 3 months comprised a disability-related variable for the acute patients, and of nine possible clinical examination findings included in the study, one variable ('pain on flexion') was independently associated with improvement for the subacute/chronic cohort. This finding contrasts with a previous Norwegian study of chiropractic LBP patients [115] as the authors reported that none of the clinical examination findings, including pain on flexion of the lumbar spine, had any predictive value albeit in a cohort of persistent LBP patients, that in contrast to this present study were additionally defined by a previous duration of 30 days or more in the previous 12 months.

In the longer term (at 6 months), disability-related variables were retained in the predictive models, a finding that is supported by another prognostic study by Bolton and Hurst in the UK [119]. Interestingly, acute patients had greater odds of improving in the longer term if they had not previously consulted the same chiropractor; however, it was not possible to differentiate patients who had previously consulted a different chiropractic from those that were naïve to chiropractic in this study presented here. It is perhaps not surprising that the predictor variables identified in the longer term differed from those in the short term. As previously described by Leboeuf-Yde *et al*. [114], this may typically reflect the LBP 'event' experienced in the short term compared to the long term LBP 'disease' which are consequently characterised by different sets of predictor variables.

Apart from 'enough time', no other baseline variables were shared by the acute or subacute/chronic subgroups in the final predictive models at any follow-up point despite the inclusion of baseline variables from several domains incorporating demographics,

work-related factors, clinical characteristics, physical examination findings and psychosocial factors. This compares with the results from a previous Norwegian prognostic study of 875 persistent LBP patients [114] where of 50 variables (singly and in combination) included at baseline, no more than 5 variables were retained in the multivariate models over a follow-up period of 12 months. More recently, Bolton and Hurst [119] found very few baseline predictor variables that were identical in both acute and persistent LBP patients. This is in contrast to a previous prognostic study of LBP patients in primary care [105] where similarities in prognostic factors between acute and chronic LBP subgroups were reported. However, Grotle *et al.* [105] defined the acute and chronic subgroups by LBP duration of less or greater than 3 months respectively, whereas Leboeuf-Yde *et al.* [114] categorised persistent LBP patients according to duration of 2 weeks at baseline coupled with more than 30 days of LBP in the past year. Furthermore, persistent LBP patients in the study conducted by Bolton and Hurst [119] were defined by LBP duration of 6 weeks at the initial consultation. Clearly, this disparity in the definition of duration categories between these studies and the present study makes direct comparison problematic.

Previous findings and those reported here, appear to reinforce a growing consensus in the literature that predictive models solely consisting of baseline variables may be at best elusive, and at worst, absent altogether. In other words, providing chiropractors with robust advice as to which patients at the initial consultation will later report improvement or non-improvement may not be feasible. Alternatively, predictive factors may only become apparent once the course of treatment has commenced. Studies are emerging that suggest early change may be of greater prognostic utility than variables recorded at baseline [109, 111, 114, 115, 117, 118].

9.4.2 Change score variables

There are only a small number of studies that have collected daily pain data utilising electronic palm-top computers from patients with chronic low back pain [172, 173]. However, there are no studies to date in the literature regarding changing pain status

over consecutive days in the first week following treatment in chiropractic LBP patients that enable direct comparison of the findings from this study.

Previous prognostic studies in chiropractic LBP patient populations have recorded outcomes at the 2nd visit [109-111, 115, 118], or *via* SMS after one week at the earliest [17, 143, 136]. However, early change in patient-reported improvement has emerged as a consistent predictor of outcome in these studies in the short term (4th visit) and up to one year later [112, 114]. Furthermore, these finding are supported by a recent UK study that reported improvement in the short term (at 4/5th visit) predicted improvement at the 10th visit in patients with persistent LBP [119]. In the study presented here, early global improvement (4th visit) was significantly associated with improvement in the medium and long term in both duration subgroups; however, it was only retained in the final prognostic model at 6 months for the subacute/chronic patients.

Importantly, and unique to this study however, was the observation that changes in pain scores recorded *via* SMS in the immediate short term predicted improvement in both duration subgroups in the short and medium term. Furthermore, when combined with the baseline variables significantly associated with improvement, only the pain change scores were retained, suggesting that these very early changes in pain are perhaps more robust prognostic indictors of recovery than the variables measured at baseline in this study. Indeed, the importance of early change as a predictor of outcome in chiropractic LBP patient populations, as opposed to the emphasis on baseline variables, is gaining prominence in the literature [118, 119].

Interestingly, there were no prognostic models that included pain change scores for either cohort at 6 months, suggesting that the influence of this very early change may be attenuated in the longer term. This could be for a number of reasons including patients that have subsequently entered another episode of LBP by this time, further emphasising the fluctuating nature of LBP [3] or entrenching of the initial condition.

In the study presented here, with regard to the assessment of pain, although instruments such as a numerical rating scale utilised here solely provide information as to the level of pain intensity, there are additional instruments that would be appropriate for rating the affective domain of pain [37]. An example of such an instrument would be the FACES scale [174] which consists of a series of drawings of facial expressions expressing various degrees of both pain intensity and the emotional impact of pain (ranging from untroubled to intense).

Predictive models were also constructed for changes in the BQ sub-scales from baseline to each follow-up (4th visit, 3 months and 6 months). A greater magnitude of change was seen in the acute cohort compared to the subacute/chronic group across all the BQ sub-scales from baseline to each successive outcome point. These findings are consistent with those reported by a similar prognostic study conducted in the UK [119].

Short and medium term changes in the BQ sub-scales of pain, disability, work fear-avoidance beliefs and locus of control were significantly associated with improvement in the acute cohort at 3 and 6 months follow-up. Unlike the acute patients, change scores in depression and anxiety were significant for the subacute/chronic cohort, emphasising the psychological component of chronicity [161]. Moreover, change in depression in the short term remained in the predictive model for improvement at 3 months in this cohort of patients. This perhaps further emphasises the impact of the affective domain of pain i.e. negative emotion and memories associated with the pain experience in this duration subgroup [38].

In the BQ prognostic models, a greater change in pain in the short term (at 4th visit) predicted improvement at 3 months in the acute patients, whereas this was somewhat protracted for the subacute/chronic patients as change in pain in the medium term (at 3 months) predicted only improvement at 6 months. On combining the significant BQ sub-scale change scores with the significant baseline variables in the multivariate analysis, early change in disability in activities of daily living was retained in the final

model for the acute patients at 6 months effectively 'over-riding' the significant baseline variables and further emphasising the importance of early change in this study as a prognostic indicator for future outcome.

9.5 Strengths and limitations

The study presented here was the first prognostic study to date conducted in the UK chiropractic patient population to utilise text messaging as a data collection tool, and to collect patient-reported pain status over consecutive days in the immediate short term *via* SMS. Furthermore, the impact of the patient-practitioner relationship had not previously been reported in a prognostic study of a chiropractic LBP patient population.

Generalisability

As data were collected in over 60 clinics throughout the UK, this potentially enhances the generalisability of the study's findings by more closely reflecting the typical day-to-day clinical practice. Despite this study being conducted in multiple centres, it only involved practising BCA members, a sub-section of the chiropractic practitioner population, which may result in reduced generalisability to the wider chiropractic profession. However, previous survey data has shown BCA to have the largest membership of the professional associations [158, 159] and as such may constitute a fair representation of this practitioner group. However, caution must still be exercised when extrapolating the results to chiropractors from other associations in the UK or indeed other countries. Furthermore, as a prospective cohort, this study cannot comment on treatment effect, as the design lacks a control group or any randomisation. Indeed this factor may be thought of as confounding the natural history of the condition.

There were no significant differences in age or gender distribution between participant and non-participant LBP patients at baseline in this study. Indeed, a strength of this study is that data were obtained from non-participants, thereby enabling the comparison

of demographic data. In order to minimise bias, the chiropractors were required to enrol consecutive LBP patients, although a limitation of this and similar studies is the reliance on practitioners (and their practice staff) to accurately follow the data collection protocol.

Further potential sources of bias in this study may include obsequious bias from patients feeling obliged to report positive outcome, particularly at the 4th visit follow-up in the clinic although it is not known to what extent the patients completed the outcomes questionnaires on their own in this setting. As the chiropractors were recruited as a convenience sample, this may introduce respondent bias as these practitioners volunteered to participate.

Loss to follow-up in longitudinal studies is a potential limitation of the study design, and in the study presented here almost 70% of patients had dropped out by the final outcome point (6 months). Nevertheless, this figure has been shown to be acceptable in clinical studies where the response rate was 32% [175]. At follow-up in the short term, there was no significant difference in age or gender distribution between responders and non-responders in this present study in either duration subgroup with the exception of the SMS study in which acute patient non-responders were more likely to be male compared with the 7-day responders. Furthermore, at follow-up points in the medium and longer term, the non-responders were more likely to be younger and male, which resembles the profile of patients that withdrew from studies similar to the study presented here, one of which also utilised SMS as a data collection tool [17, 113]. This potentially impacts on the generalisability of the findings, as the non-responders at later follow-up points may represent a different group to the responders. It is not known whether the patients that dropped out of this study stopped participating due to improvement in their LBP status.

A limitation regarding loss to follow-up in this study may be that no reminders were sent to those patients who failed to return the postal questionnaire at 6 months.

Interestingly, although reminders sent to patients *via* SMS for the 3 month postal follow-up generated a considerably higher response rate when sent prior to receiving the postal questionnaires as opposed to after; those patients who did not receive any reminder actually had the highest response rate to the questionnaire. This finding questions the utility of sending reminders to non-respondents, certainly in this study.

Data preparation and analysis

Errors may occur when manually transcribing data from paper questionnaires to a spreadsheet or data analysis software program. Consequently, prior to conducting the inferential analysis, frequency distributions were conducted that revealed few errors had occurred in this process, and additionally, a random sample of 10% of cases was re-checked by the author (LD). Furthermore, the SMS responses received from patients were automatically entered into a spread sheet thereby eliminating manual data input errors.

Logistic regression analysis is one appropriate method for identifying a significant association of an independent variable with a dichotomous outcome or dependent [176, 177] and was consequently utilised for the inferential analysis in this study. Univariate and multivariate logistic regression analyses were initially conducted utilising the Complex Samples Logistic Regression procedure in SPSS to account for the potential effect of individual practitioners. These results were subsequently compared with analysis conducted without the Complex Samples procedure, whereby only negligible differences were noted suggesting that the effect of individual practitioners was not a confounder in this study.

The results from the univariate and multivariate logistic regression analyses produced several large odds ratios with wide confidence intervals for significant predictor and outcome variable associations. Plausible reasons for the imprecise estimates are that the

numbers of participants in some of the categories (of the predictor variables) were small and also that there were greatly reduced numbers of non-improved patients at follow-up compared to improved patients, further reducing the numbers in some cells. Moreover, the sample size was small compared to similar predictor studies [109-111, 114, 117, 119] that had approximately double the number of participants included in the data analysis and fewer variables at baseline than the study presented here, and therefore may be more statistically robust [153, 178].

Problems may arise with results from multivariate logistic regression analysis when there are too few outcome events relative to the number of predictor variables [179, 180] and a guideline "rule of thumb" has therefore been proposed for a minimum number of 10 events *per* variable (EPV) in multivariate analysis [176, 180]. Furthermore, the events are defined by the smaller category of the binary outcome variable, which in the study presented here equates to the patients that were not improved of which there were considerably fewer than improved patients at each follow-up. Consequently the EPV was rather small, potentially leaving too few non-improved patients for robust analysis.

Additionally, those cases with any missing data points are not included in the analysis (list or case-wise deletion) and as such only complete case analysis is conducted by the software programme SPSS. In the study presented here, for several of the multivariate analyses this amounted to approximately 50% of cases and may have introduced further bias to the estimates as these cases were not deleted completely at random. Although imputation of data may be used in this type of study design, following on from statistical advice (Dr Reuben Ogollah, personal communication, 2011; 2012), multiple imputation was considered to be inappropriate within the time frame available for the missing data in the study presented here due to the complexity of this method. However, this is acknowledged as a potential limitation.

Text-messaging study

The use of text-messaging as a data collection tool may be considered a strength of this study as it permits very frequent follow-ups, unlike using conventional paper questionnaires. It is increasingly being used as a data collection tool as it is user-friendly, relatively inexpensive and less time-consuming for the researcher [17, 142-144, 181-183]. Furthermore, as the vast majority of the population have a mobile phone it is not solely limited to younger people [183] and it can be readily accessed by a range of study participants. The E-Communications Household Survey (2006) [184] reported that in European Union Member States, possession of a mobile phone ranges from 95% in 15 to 24 year olds, 85% for 40 to 54 year olds and 55% for those aged over 55 years. A similar pattern is also seen in other developed countries [183]. Furthermore, using SMS means that the data is captured in real time [185] as people tend to keep their mobile phone with them and respond quickly thereby reducing recall bias and perhaps providing a truer picture of the participant's LBP status [183]. Questions sent *via* SMS are required to be concise and although this may be a limitation in some situations, it did not appear to be so in this study presented here. Similarly, as the responses simply consisted of a digit, very few erroneous responses were received from the participants in this study.

In the study presented here, of all patients who participated in the SMS study, the response rate was high as 86% of acute and 93% of subacute/chronic patients responded on the 7th day. Furthermore, this did not fluctuate greatly over 7 days demonstrating that few patients withdrew and suggesting that there was limited participant fatigued despite the daily frequency of the text messages over a week. Although a greater proportion of acute than subacute/chronic patients withdrew from the SMS study, it is not known whether this was due to improvement in their LBP status.

Overall, the response rate of this data collection method in similar studies of chiropractic LBP patients has been quite high [17, 142-144]. Findings from a recent Swedish study [144] that recorded SMS responses from LBP patients on a weekly basis over 6 months concluded that telephone reminders to non-responders had been important in the boosting response rate by almost 20% to a mean response rate of 83%. In a similar

study in Denmark conducted over 18 weeks, the lower response rate (63%) was attributed to not having conducted telephone reminders [17]. Similarly, in low back pain research, a recent observational study nested within a randomised controlled trial conducted by Macedo *et al*. [182] assessed the feasibility of using SMS (to record average pain levels). Although participants were contacted *via* SMS once a month over a period of 12 months, the response rate increased from approximately 60% for SMS alone to over 95% when supplemented with telephone interviews. However, due to the frequency of the text messages in the study presented here, it was not feasible to contact non-responders on a daily basis. Although this may be a potential limitation of the study, the response rate was comparable with other similar studies that utilised reminders.

Several clinicians withdrew from the study presented here stating that they did not want their patients to incur any cost for the SMS replies, although this costing had been detailed in the chiropractor information, the patient information and conference presentations delivered to the profession prior to the onset of the data collection. It is not known whether patients themselves chose not to participate for this reason. However, a recent Swedish study that utilised SMS on a weekly basis with chiropractic LBP patients [144] reported that only one patient withdrew from the study due to the cost of the text messages. In the study presented here, although the patients were required to cover the cost for their SMS replies (a maximum of 15), those participants with a mobile phone contract would already have a specific number of text messages included as part of the contract arrangement. However, it was not possible to discern the proportion of patients that had a mobile phone contract in this study.

Although there were no SMS data entry errors due to automation of the system (as previously described), patients documenting their mobile phone number on the baseline questionnaire potentially increases the likelihood of error. As patients sent a text-message from their mobile phone to the number provided at the end of the baseline questionnaire, this mobile phone number was logged as belonging to the patient. If there was a discrepancy between the written mobile phone number and the number used

to send the text, then the patient's questionnaires could not be subsequently linked-up with their SMS responses (the proportion of mobile phone users in the general population that can correctly state their number is unknown). However, this was considered the only feasible way to ensure patients received the first SMS question the day after the initial consultation. Approximately 20% of the SMS responses could not be correctly linked-up with the relevant questionnaires in this study, and hence the identification of the patient, thereby resulting in loss of data and is a limitation of this study.

Two SMS questions *per* day were sent to participants, enquiring about pain and global improvement (PGIC). However, due to an error in the wording of the PGIC question which erroneously referred to change over each subsequent 24 h, this question did not capture change as related to status at baseline. Consequently, only the PGIC data from day 1 was able to be used in the analysis. Short term improvement at the 2nd visit has been shown to predict outcome at the 4th visit [109, 111, 115], and the 2nd visit is typically within the first week following consultation, however, it was not possible to compare this outcome with other studies within the context of this time frame.

The analysis of repeated measures (such as the SMS data in this study) involves accounting for within-subject correlation and for the effect of time. Indeed, this method is beginning to emerge in the literature as a means of accounting for within-subject correlation in the analysis of repeated data [186]. However, it was not possible to implement this complex statistical method in this study presented here due to time constraints, and as such this may have limited the utility of the prognostic models (Dr Reuben Ogollah, personal communication, 2011; 2012). Nevertheless, although logistic regression was utilised, it is supported by the vast majority of similar prognostic studies of chiropractic LBP patients [111, 115, 117-119].

9.6 Considerations for further research

The findings from this study highlight the importance of early change as a prognostic factor and suggest that in conjunction with previous prospective studies, the utility of baseline variables as prognostic factors may be limited. However, the inclusion of the patient-practitioner relationship has emerged as a predictor of outcome in the short term in both acute and subacute/chronic LBP patients in this study and therefore warrants further investigation.

9.7 Conclusion

The investigation presented here describes an attempt to predict improvement in acute and subacute/chronic LBP patients undergoing chiropractic treatment in the UK. Unique to this research project were the inclusion of the therapeutic alliance as a potential predictor of outcome and the use of text-messaging to collect data over 7 consecutive days following the initial chiropractic consultation.

This study contributes to the body of research concerning prognostic factors in the UK chiropractic LBP population, specifically those in the immediate short term. Although several baseline predictor variables were identified, the discriminative ability of the multivariate models ranged from weak to acceptable in the acute and subacute/chronic cohorts respectively. There was little consistency in the prognostic models of baseline variables between the duration subgroups at successive follow-ups with the exception of the therapeutic alliance, suggesting that the patient-practitioner relationship may have an impact on outcomes for LBP patients presenting to a chiropractor in the UK at least in the short term as reported in the study presented here. Furthermore, early and medium term change variables predicted outcome in the medium and long term, reflecting the emerging predictive utility of change variables, as previously reported by several authors.

From a clinical perspective, the findings from this study would suggest that those LBP patients receiving chiropractic care who do not show improvement during the very early and medium course are more likely to have a poorer prognosis both in the medium and long term. Early improvement and the inclusion of change variables are emphasised as being of key importance in future prognostic studies of LBP patients receiving chiropractic care.

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Appendices

Appendix 1: Transcribed comments received from Peer Reviewers

Appendix 2: Chiropractor Recruitment Form

Appendix 3: Questionnaires, Patients Information Sheet, Informed Consent Forms

Appendix 4: Operations Manual, Step-By-Step Instructions, Flow Chart, Data Collection Envelope, letter to chiropractor, letter to clinic reception staff

Appendix 5: Text-messaging – questions and messages

Appendix 6: Letter of ethics approval from the AECC Ethics Sub-Committee

Appendix 1: Transcribed comments received from Peer Reviewers

Peer Reviewer 1:

- Recruiting through reception staff over the phone brings in problematic logistical and ethical issues. Omit screening patients before their appointment.
- New patients are frequently asked to arrive about 15 minutes early for their appointments to complete clinic paper work.
- Use a checklist (tick boxes) for data collected.
- Use a screening list on the Informed Consent Form.
- PQV1: took 8 minutes to complete (PIS and ICF 3 and 1 minute respectively).
- CRFV1: complete when patient is completing PPQV1.
- PQV1: more space needed on Q16 (patient's height)
- CRFV1: asking about "immediate improvement" (Q9) is too subjective.
- PPQV1: patient's answers about exercise and lifestyle (they're not medically qualified to judge this).
- PQV4: follow-up if patient drops out before 4th visit?
- PQV at 3 and 6 months: no mention of when this is used (in Ops Manual)

Peer Reviewer 2:

- Operations Manual: omit list on front page (covered in the accompanying letter).
- Various amendments of phrases throughout the Manual: condense/uncomplicated.
- New patients are frequently asked to arrive about 15 minutes early for their appointments to complete clinic paper work.
- Patients may not want to talk to a receptionist on the phone about personal health issues and therefore screening over the phone probably won't work.
- What is the cost of the texts to the patient?
- Reduce amount of caps/bold/underlining.
- Ensure type face is consistent throughout all the study documents.
- PIS: decrease number of words/simplify.
- ICF: larger tick boxes required.

Peer Reviewer 3:

- Expect that the forms at 1st visit will take 30-45 minutes to complete (too much time).
- Font size is too small.
- New patients are frequently asked to arrive about 15 minutes early for their appointments to complete clinic paper work.

Peer Reviewer 4:

- Operations Manual: too complicated and detailed for most DC's / too many words.
- Omit contents on first page of Operations Manual.
- Keep type face consistent throughout (ideally not Times New Roman!).
- Simplify the process by using different coloured forms (and refer to these as the "yellow form" on the instructions).
- Simplify the Step-By-Step instructions and Flow Chart. Do you need both?
- Specify patient is a regular mobile phone user (reply and send texts).
- Clarify "consecutive" patients (taken from those who consent to participate).
- Screen patients for eligibility at the 1st visit not over the phone.
- Ask all patients to bring their mobile phone with them.
- Unnecessary repetition in the Operations Manual of inclusion/exclusion criteria.
- Use different forms in different colours.
- Cost of sending texts to the patient?
- PIS: patient responding "well" – rephrase?
- CRFV1: define lateral flexion as uni or bilateral (Q6).
- CRFV1: put patient inclusion criteria in bullet points.
- CRF: 40+ hours? (Q7).
- PQV1: more space on Q16 (patient's height).
- PQV1: 3-6days, 1-2 weeks? (Q17).
- PQV1: why the same DC? (Q29).
- PQV1: relate compensation to fault? Or is this inherent in the question? (Q32).

Peer Reviewer 5:

General comments:

- "I found this to be a very well designed study with clear instructions for practitioners and patients alike. I would not have any major difficulties in applying the instructions as they are set out in the Operations Manual or in using the data collection forms. Most of the questions within the various questionnaires are clearly worded".

- How will chiropractors be informed about the study for the **first** time and **before** they will receive the Chiropractor Recruitment Form and the 'thank you for agreeing to participate letter'? Will there be any initial letter or announcement(s) via the different associations? If so, it may be of benefit to get the direct support from the CEO or President of the association in order to achieve a good participation rate by members.

Specific comments:

- The 'Dear Colleague letter' and the Operations manual refer to the **Patient Information Sheet**, this is however titled **Participant** Information sheet. Please change accordingly throughout the documentation to ensure consistency.

- On page 1 of the Operations Manual reference is made to the inclusion criteria for patients – under the first bullet point a 'new episode of low back pain (as the main complaint) of any duration' is given. Perhaps further clarification should be given to the chiropractors on what exactly defines a **new episode.** Further, the remainder of the documentation and material does not refer to new episode of LBP but only LBP elsewhere – so perhaps a minor inconsistency here.

- Step-by-step instructions – 4a '….puts **it**…' and 6 '…All data **have** been…'

- Patient Questionnaire Visit 1 –
- Q18 '…which of the following **describe** your pain…'
- Q13 '…How do you expect your current…'
- Q34 '…yes, for 3 **to** 6 weeks…'

- Patient-Practitioner Questionnaire Visit 1 –
- Q1 perhaps you need more than just the name to identify the patient, in case there are two Mr Smiths, etc.? Add date of birth? The same may apply to the questionnaires for Visit 4 and 3 and 6 months?

- Patient Questionnaires Visit 4, 3 months and 6 months – Q12 '…**status**…'

Peer Reviewer 6:

- Amend Chiropractor Letter (accompanying Operations Manual) regarding start date of data collection.
- Clarify what is meant by 'existing' patients.
- Completing forms at 1st visit will take longer than 10 minutes.
- If receptionist isn't screening patient over the phone – patients should at least be told the clinic is taking part in a study (they will receive more information at their appointment and whether they agree or not to take part this will not affect their chiropractic treatment).
- Consent – how valid is it if the patient signs consent form immediately after reading information sheet?
- Operations Manual – repetitive and too detailed.
- PPQV1: keep knowledge of content away from chiropractors as this may bias their behaviour towards the patient. (this Reviewer currently involved with assessing patient satisfaction with GPs – they have not seen the questions being used for the patients).
- Clarification about when the patient completes PQV4 (after treatment rather than during) and how will the chiropractor know to give this questionnaire to the patient? This is not clear.

- Several suggested amendments to Participant Information Sheet.
- Why is the last follow up not longer than 6 months?
- CRF: age and time in practice in ‘years’
- Pre-code patients’ identification rather than using names?
- PQV1: layout a bit jarring in places.
- PPQV1: tick box option for Q4 and Q5.

Appendix 2: Chiropractor Recruitment Form

Chiropractor Recruitment Form

Completion of this form is required as a record of your agreement to participate in this study. The data you provide will be treated in confidence and anonymously. Please note that more than one chiropractor can participate from one practice, but EACH chiropractor must complete an individual Chiropractor Recruitment Form. A more detailed outline of the study will be given in the Operations Manual (which you will receive in the near future).

Q1 Your name:

Q2 Your practice address (including Postcode):

Q3 Contact telephone number(s) including STD code:

Q4 Contact email address: (PLEASE PRINT)

Please tick ONE box to answer each of the following questions:

Q5 Are you?

- Male ☐
- Female ☐

Q6 What is your age?

- Less than 25 years ☐
- 26 to 35 years ☐
- 36 to 45 years ☐
- 46 to 55 years ☐
- 56 to 65 years ☐
- More than 65 years ☐

Q7 How many years have you been practising as a chiropractor?

Q8 On average, how many hours each week do you see patients? (TICK ONE BOX)

- 0-9 hours ☐
- 10-19 hours ☐
- 20-39 hours ☐
- 39+ hours ☐

Q9 For the most part, how do you work? (TICK ONE BOX)

- As a sole practitioner (WITH Receptionist assistance) ☐
- As a sole practitioner (WITHOUT Receptionist assistance) ☐
- In premises with another chiropractor(s)/other healthcare practitioners ☐

Thank you for agreeing to participate and completing this form

Appendix 3:

Questionnaires, Patients Information Sheet,

Informed Consent Form

Patient Questionnaire Visit 1

The following questions are about you and your LOW BACK PAIN. The information you give will be treated in confidence and anonymously. We do need your name and address however to send you future questionnaires. Please answer ALL the questions IN ORDER as honestly as you can.

Q1 What is your name?

Q2 How old are you?

Q3 Are you? (tick ONE)

Male ☐ Female ☐

Q4 Do you live alone? (tick ONE)

Yes ☐ No ☐

Q5 What is the highest level of education you completed? (tick ONE)

Secondary school ☐ College/ University ☐

Q6 What is your mobile phone number?

Q7 What is your address (include postcode)?

Q8 What is today's date?

Please answer the following questions about your LIFESTYLE.

Q9 Are you currently a REGULAR smoker? (tick ONE)

No ☐ Yes (More than 20 a day) ☐

Yes (Less than 20 a day) ☐

Q10 In the past month, how often were you physically active in your day-to-day routine (e.g. walking, gardening, housework, child care, cycling, sports such as swimming, golf and football)? (tick ONE)

Most of the time ☐ Almost never ☐

Some of the time ☐

Q11 In the past month, how many times a week did you participate in strenuous physical exercise (enough to make you sweat and increase your heart rate)? (tick ONE)

None ☐ Three or more times ☐

Once or twice ☐

The following questions are about your GENERAL HEALTH.

Q12 APART FROM YOUR LOW BACK PAIN, do you have any other health problems for which you are receiving regular treatment? (tick ONE)

Yes ☐ No ☐

Please specify:

PLEASE TURN OVER

Q13 Overall, APART FROM YOUR LOW BACK PAIN, how would you rate your general health as compared to others of your age? (tick ONE)

- Much better ☐
- Better ☐
- About the same ☐
- Worse ☐
- Much worse ☐

Q14 Overall, how often do you feel the stresses of daily life affect you and your general well-being? (tick ONE)

- Constantly ☐
- Most of the time ☐
- Some of the time ☐
- Rarely ☐

Q15 What is your weight?

EITHER in Stones and pounds ___ OR in Kilograms ___

Q16 What is your height?

EITHER in Feet and Inches ___ OR in Centimetres ___

The following questions are about your CURRENT EPISODE OF LOW BACK PAIN.

Q17 For how long have you had this CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

- 1 to 2 days ☐
- 3 to 7 days ☐
- 1 to 2 weeks ☐
- 2 to 6 weeks ☐
- 6 weeks to 3 months ☐
- More than 3 months ☐

Q18 Throughout this CURRENT EPISODE OF LOW BACK PAIN, which of the following best describes your pain? (tick ONE)

- Pain comes and goes for no apparent reason ☐
- Pain depends on what movements I make or position I'm in ☐
- Pain is there all the time ☐

Q19 Throughout this CURRENT EPISODE OF LOW BACK PAIN, when is your back pain generally at its WORST? (tick ONE)

- When I have been sitting for around more than half an hour ☐
- When I wake up in the morning ☐
- Around the middle of the day ☐
- In the evening ☐
- During the night ☐

Q20 Overall, how troublesome is this CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

- Extremely or Very troublesome ☐
- Moderately troublesome ☐
- Slightly troublesome ☐
- Not at all troublesome ☐

Q21 Do you have any problems with the following activities because of this CURRENT EPISODE OF LOW BACK PAIN? (tick as many as apply)

- Turning in bed ☐
- Sleeping ☐
- Putting on socks or shoes ☐
- Going for a walk ☐
- Getting up from sitting ☐

Q22 IN ADDITION TO THE PAIN IN YOUR LOW BACK, do you ALSO have pain in any of the following areas? (tick as many as apply)

- Neck ☐
- Head ☐
- Shoulder(s) or arm(s) ☐
- Leg(s) above the knee(s) only ☐
- Leg(s) spreading below the knee(s) ☐

Q23 If you DO HAVE LEG PAIN in addition to your low back pain, is this? (tick ONE)

Constant ☐ On and off ☐

CONTINUED ON NEXT PAGE

Please tick ONE box for each of the following questions that best describes your CURRENT EPISODE OF LOW BACK PAIN and how it is affecting you NOW.

Q24 Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q25 Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q26 Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q27 Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q28 Over the past few days, how depressed (down-in-the-dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q29 Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10 is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it no worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q30 Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q31 Have you ever been treated BEFORE by the chiropractor you are seeing today? (tick ONE)

Yes..... ☐ No..... ☐

PLEASE TURN OVER

Q32 Do you have private health insurance that covers payment for your chiropractic treatment? (tick ONE)

- Yes, fully covered ☐
- Yes, partially covered ☐
- No, not covered ☐
- Not sure ☐

Q33 How do you expect your CURRENT EPISODE OF LOW BACK PAIN to respond to treatment? (tick ONE)

- Fully recover ☐
- Partially recover ☐
- Probably not recover ☐
- Definitely not recover ☐

Q34 Have you made (or considering making) a CLAIM for compensation for this CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

Yes ☐ No ☐

Q35 Are you receiving any illness or disability BENEFIT for this CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

Yes ☐ No ☐

The following questions are about any LOW BACK PAIN you may have had IN THE PAST.

Q36 When was the FIRST TIME you ever experienced LOW BACK PAIN? (tick ONE)

- Never before ☐ Go to Q40
- Within the past year ☐ Continue on to Q37
- 1 to 5 years ago ☐ Continue on to Q37
- 5-10 years ago ☐ Continue on to Q37
- More than 10 years ago ☐ Continue on to Q37
- Can't remember ☐ Continue on to Q37

Q37 OVER THE PAST 12 MONTHS, how many days IN TOTAL have you suffered from low back pain? (tick ONE)

- 30 days or less low back pain on and off ☐
- 30 days or less constant low back pain ☐
- More than 30 days low back pain on and off ☐
- More than 30 days constant low back pain ☐

Q38 For your LOW BACK PAIN IN THE PAST, have you ever made a CLAIM for compensation? (tick ONE)

Yes ☐ No ☐

Q39 For your LOW BACK PAIN IN THE PAST, have you ever taken TIME OFF from paid work? (tick ONE)

- Yes,once for no more than a few days ☐
- Yes, once for longer than a few days ☐
- Yes, several times ☐
- No ☐

The following questions concern your WORK STATUS.

Q40 Irrespective of whether you are off work because of your low back pain, are you normally in PAID WORK? (tick ONE)

- Yes, employee ☐ Go to Q41
- Yes, self-employed ☐ Go to Q41
- No ☐ Now send text (see over page)

CONTINUED ON NEXT PAGE

As you answered that you were NOT IN PAID WORK, PLEASE NOW SEND A TEXT MESSAGE using the single word GO to the following number: 07531375711. Thank you for your time in completing this questionnaire

If you ARE IN PAID WORK/EMPLOYMENT, please answer the remaining questions.

THE FOLLOWING QUESTIONS ARE ABOUT YOUR WORK

Q41 Which one of the following best describes your activities AT WORK? (tick ONE)

- MAINLY heavy manual work ☐
- MAINLY light manual work ☐
- MAINLY walking or standing ☐
- MAINLY sitting ☐

Q42 Does your WORK involve you in doing any of the following? (tick as many as apply)

- Frequent bending and/or twisting of your back ☐
- Frequent driving of any of the following: car/van/forklift truck/lorry bus/coach/agriculture vehicle ☐
- Frequent lifting and/or carrying ☐

Q43 Does your WORK involve working shifts? (tick ONE)

Yes ☐ No ☐

Q44 Overall, are you SATISFIED with your WORK/JOB? (tick ONE)

- Very satisfied ☐
- Satisfied ☐
- Neither satisfied nor dissatisfied ☐
- Dissatisfied ☐
- Very dissatisfied ☐

The following questions relate to how your CURRENT EPISODE OF LOW BACK PAIN is affecting your WORK.

Q45 Have you taken any SICK LEAVE for your CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

- No, I have not taken time off work ☐
- Yes, for 1 to 2 days ☐
- Yes, for 3 to 7 days ☐
- Yes, for 1 to 3 weeks ☐
- Yes, for 3 to 6 weeks ☐
- Yes, for 6 weeks to 3 months ☐
- Yes, for more than 3 months ☐

Q46 Have you changed to LESS DEMANDING tasks at work because of this CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

Yes ☐ No ☐

Q47 Do you feel that your employer(s) is(are) generally supportive about your CURRENT EPISODE OF LOW BACK PAIN? (Tick ONE)

Yes ☐ Not relevant ☐

No ☐

Q48 Do you feel that your work colleagues are generally supportive about your CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

Yes ☐ Not relevant ☐

No ☐

Q49 Do you feel that your WORK is PREVENTING you making a full recovery from your CURRENT EPISODE OF LOW BACK PAIN? (tick ONE)

Yes ☐ No ☐

PLEASE NOW SEND A TEXT MESSAGE using the single word GO to the following number: 07531375711. Thank you for your time in completing this questionnaire

Chiropractor Recording Form Visit 1

Please answer the following questions. Before you do, please make sure that this patient meets ALL the following: 18-60 years; no treatment for low back pain in previous 3 months; low back pain of any duration (located between the costal margins/ T12 and the lower gluteal folds) as the main complaint with or without leg pain; not pregnant. Please ensure the patient has signed the Informed Consent Form.

Q1 Patient's name:

Q2 Today's date:

Q3 Does this patient have any contraindication (s) to chiropractic care? (tick ONE)

Yes ☐ Patient exits. Put form in Data Collection Envelope

No ☐ Go to Q4

Q4 Type of onset of this CURRENT episode of low back pain: (tick ONE)

Sudden ☐ Gradual ☐

Q5 Mode of onset of this CURRENT episode of low back pain: (tick ONE)

Trauma ☐ Insidious ☐

Effort ☐ Other ☐

Q6 According to the patient, is this CURRENT low back pain localised to one side of the lumbar spine? (tick ONE)

Yes ☐ No ☐

Q7 Please indicate any lumbar ranges of motion that provoke the patient's low back pain: (tick as many as apply)

Flexion ☐ Rotation ☐

Extension ☐ Test not done ☐

Lateral flexion ☐

Q8 On examination, does the patient's low back pain momentarily 'catch' at a specific point during movement? (tick ONE)

Yes ☐ Test not done ☐

No ☐

Q9 Is the patient's low back pain readily provoked on palpation? (tick ONE)

Yes ☐ Test not done ☐

No ☐

Q10 Does the patient have LEG PAIN in addition to low back pain? (tick ONE)

Yes ☐ Go to Q11 No ☐ Go to Q14

Q11 Are positive nerve root signs present (e.g. positive SLR/positive slump test/lower limb myotomal weakness/ dermatomal sensory loss/ hypo-reflexia)? (tick ONE)

Yes ☐ Possibly ☐

No ☐ Test not done ☐

Q12 IF THE PATIENT HAS LEG PAIN, does repeated lumbar FLEXION (ten times in a row with the patient standing) reproduce or aggravate the leg pain, or cause the leg pain to move distally? (tick ONE)

Yes ☐ Test not done ☐

No ☐

Q13 IF THE PATIENT HAS LEG PAIN, does repeated lumbar EXTENSION (ten times in a row with the patient standing) relieve the leg pain, or cause the leg pain to move proximally? (tick ONE)

Yes ☐ Test not done ☐

No ☐

Q14 Did the patient's low back pain (and/or leg pain if appropriate) linger at the end of the routine examination? (tick ONE)

Yes ☐ No ☐

PLEASE TURN OVER

Q15 Was an immediate improvement after the treatment felt by the patient today? (tick ONE)

Yes..... ☐ No..... ☐

Q16 How do you expect this patient's low back complaint to have responded by 3 months? (tick ONE)

Fully recovered .. ☐ Not sure..... ☐

Partially recovered..... ☐

Q17 Based on your clinical experience, how would you rate this patient's overall physical constitution on a scale where '0' is 'very fragile' and '10' is 'very robust'? (tick ONE)

	0	1	2	3	4	5	6	7	8	9	10
Very fragile	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q18 Based on your clinical experience, how would you rate this patient's overall mental/emotional resilience on a scale where '0' is 'very fragile' and '10' very robust'? (tick ONE)

	0	1	2	3	4	5	6	7	8	9	10
Very fragile	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Thank you for your time in completing this form. Please now put this form in the patient's DATA COLLECTION ENVELOPE and keep this with the patient's file.

Patient-Practitioner Questionnaire Visit 1

The following statements are about how you may be thinking or feeling about the consultation with your chiropractor TODAY. The information you give will be treated in confidence and WILL NOT BE SEEN BY YOUR CHIROPRACTOR. We do need your name however to link up your questionnaires. Respond to ALL the statements IN ORDER as honestly as you can.

Q1 What is your name?

Q2 What is today's date?

Please tick ONE box for each of the following statements that best describes how you feel.

Q3 So far, I feel I have had enough time with my chiropractor today. '0' is 'strongly agree' and '7' is 'strongly disagree'. (tick ONE)

	0	1	2	3	4	5	6	7
Strongly agree	☐	☐	☐	☐	☐	☐	☐	☐

Q4 I feel that my chiropractor understands what is wrong with my low back and can help me. '0' is 'strongly agree' and '7' is 'strongly disagree'. (tick ONE)

	0	1	2	3	4	5	6	7
Strongly agree	☐	☐	☐	☐	☐	☐	☐	☐

Q5 My chiropractor and I agree about the things (e.g. exercises/lifestyle changes) I will need to do to help my low back problem. '0' is 'strongly agree' and '7' is 'strongly disagree'. (tick ONE). (If you have NOT discussed this with your chiropractor, please leave blank).

	0	1	2	3	4	5	6	7
Strongly agree	☐	☐	☐	☐	☐	☐	☐	☐

Q6 My chiropractor and I have a good understanding about the goals (e.g. for recovery and prevention in the future) we are working towards for my low back problem. '0' is 'strongly agree' and '7' is 'strongly disagree'. (tick ONE). (If you have NOT discussed this with your chiropractor, please leave blank).

	0	1	2	3	4	5	6	7
Strongly agree	☐	☐	☐	☐	☐	☐	☐	☐

Thank you for your time in completing this form. Please now put this form in the envelope provided, seal the envelope and hand it to your chiropractor.

Patient Questionnaire Visit 4 (OR earlier visit if treatment concluded sooner)

The following questions are about you and your LOW BACK PAIN. The information you give will be treated in confidence and anonymously. We do need your name however to link up your questionnaires. Please answer ALL the questions IN ORDER as honestly as you can- there are no right or wrong answers.

Q1 What is your name?

Q2 What is today's date?

Please tick ONE box for each of the following questions that best describes your CURRENT EPISODE OF LOW BACK PAIN and how it is affecting you NOW.

Q3 Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q4 Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q5 Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q6 Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q7 Over the past few days, how depressed (down-in-the-dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q8 Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10 is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it no worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

PLEASE TURN OVER

Q9 Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q10 Do you have problems with any of the following activities because of this current episode of low back pain? (tick as many as apply)

- Turning in bed ☐
- Sleeping ☐
- Putting on socks or shoes ☐
- Going for walks ☐
- Getting up from sitting ☐

Q11 Since beginning treatment at this clinic, how would you describe the change (if any) in ACTIVITY, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE, related to your low back pain? (tick ONE)

- Worse ☐
- No change ☐
- Almost the same, hardly any change ☐
- A little better but no noticeable change ☐
- Somewhat better but the change has made no real difference ☐
- Moderately better and a slight but noticeable difference ☐
- Better and a definite improvement that has made a real and worthwhile difference ☐
- A great deal better and a considerable improvement that has made all the difference ☐

Q12 Which of the following best describes your work (employment) status at the PRESENT time with regard to sick leave? (tick ONE)

- I have had no sick leave over the past few weeks because of my back pain ☐
- I have now returned to work from sick leave because of my low back pain ☐
- I am currently on sick leave because of my low back pain ☐

Thank you for your time in completing this questionnaire.

Patient Questionnaire at 3 months

The following questions are about you and your LOW BACK PAIN. The information you give will be treated in confidence and anonymously. We do need your name however to link up your questionnaires. Please answer ALL the questions IN ORDER as honestly as you can- there are no right or wrong answers.

Q1 What is your name?

Q2 What is today's date?

Please tick ONE box for each of the following questions that best describes your CURRENT EPISODE OF LOW BACK PAIN and how it is affecting you NOW.

Q3 Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q4 Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q5 Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q6 Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q7 Over the past few days, how depressed (down-in-the-dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q8 Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10 is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it no worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

PLEASE TURN OVER

Q9 Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q10 Over the past 3 months, how much time have you been FREE FROM YOUR LOW BACK PAIN? (tick ONE)

- Most of the time I have been pain-free ☐
- A little of the time I have been pain-free ☐
- Some of the time I have been pain-free ☐
- No, I have not been pain-free at all ☐

Q11 Do you have problems with any of the following activities because of this current episode of low back pain? (tick as many as apply)

- Turning in bed ☐
- Going for walks ☐
- Sleeping ☐
- Getting up from sitting ☐
- Putting on socks or shoes ☐

Q12 Since beginning treatment at this clinic, how would you describe the change (if any) in ACTIVITY, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE, related to your low back pain? (tick ONE)

- Worse ☐
- Moderately better and a slight but noticeable difference ☐
- No change ☐
- Almost the same, hardly any change ☐
- Better and a definite improvement that has made a real and worthwhile difference ☐
- A little better but no noticeable change ☐
- Somewhat better but the change has made no real difference ☐
- A great deal better and a considerable improvement that has made all the difference ☐

Q13 Which of the following best describes your work (employment) status at the PRESENT time with regard to sick leave? (tick ONE)

- I have had no sick leave over the past 3 months because of my back pain ☐
- I am currently on sick leave because of my low back pain ☐
- I have now returned to work from sick leave because of my low back pain ☐

Thank you for your time in completing this questionnaire.
Please now return it immediately in the SAE provided.

Patient Questionnaire at 6 months

The following questions are about you and your LOW BACK PAIN. The information you give will be treated in confidence and anonymously. We do need your name however to link up your questionnaires. Please answer ALL the questions IN ORDER as honestly as you can- there are no right or wrong answers.

Q1 What is your name?

Q2 What is today's date?

Please tick ONE box for each of the following questions that best describes your CURRENT EPISODE OF LOW BACK PAIN and how it is affecting you NOW.

Q3 Over the past few days, on average, how would you rate your low back pain on a scale where '0' is 'no pain' and '10' is 'worst pain possible'?

	0	1	2	3	4	5	6	7	8	9	10
No pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q4 Over the past few days, on average, how has your low back pain interfered with your daily activities (housework, washing, dressing, lifting, walking, driving, climbing stairs, getting in/out of bed/chair, sleeping) on a scale where '0' is 'no interference' and '10' is 'completely unable to carry on with normal daily activities'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q5 Over the past few days, on average, how much has your low back pain interfered with your normal social routine including recreational, social and family activities, on a scale where '0' is 'no interference' and '10' is 'completely unable to participate in any social and recreational activity'?

	0	1	2	3	4	5	6	7	8	9	10
No interference	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q6 Over the past few days, on average, how anxious (uptight, tense, irritable, difficulty in relaxing/concentrating) have you been feeling, on a scale where '0' is 'not at all anxious' and '10' is 'extremely anxious'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all anxious	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q7 Over the past few days, how depressed (down-in-the-dumps, sad, in low spirits, pessimistic, lethargic) have you been feeling, on a scale where '0' is 'not at all depressed' and '10' is 'extremely depressed'?

	0	1	2	3	4	5	6	7	8	9	10
Not at all depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q8 Over the past few days, how do you think your work (both inside the home and/or employed work) have affected your low back pain, on a scale where '0' is 'make it no worse' and '10 is 'make it very much worse'?

	0	1	2	3	4	5	6	7	8	9	10
Make it no worse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

PLEASE TURN OVER

Q9 Over the past few days, on average, how much have you been able to control (help/reduce) and cope with your low back pain on your own, on a scale where '0' is 'I can control it completely' and '10' is 'I have no control whatsoever'?

	0	1	2	3	4	5	6	7	8	9	10
I have complete control over my pain	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Q10 Over the past 3 months, have you been FREE FROM YOUR LOW BACK PAIN? (tick ONE)

- Most of the time I have been pain-free ☐
- A little of the time I have been pain-free ☐
- Some of the time I have been pain-free ☐
- No, I have not been pain-free at all ☐

Q11 Are you still experiencing any problems with any of the following activities because of this current episode of low back pain? (tick as many as apply)

- Turning in bed ☐
- Going for walks ☐
- Sleeping ☐
- Getting up from sitting ☐
- Putting on socks or shoes ☐

Q12 Since beginning treatment at this clinic, how would you describe the change (if any) in ACTIVITY, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE, related to your low back pain? (tick ONE)

- Worse ☐
- No change ☐
- Almost the same, hardly any change ☐
- A little better but no noticeable change ☐
- Somewhat better but the change has made no real difference ☐
- Moderately better and a slight but noticeable difference ☐
- Better and a definite improvement that has made a real and worthwhile difference ☐
- A great deal better and a considerable improvement that has made all the difference ☐

Q13 Which of the following best describes your work (employment) status at the PRESENT time with regard to sick leave? (tick ONE)

- I have had no sick leave over the past 3 months because of my back pain ☐
- I am currently on sick leave because of my low back pain ☐
- I have now returned to work from sick leave because of my low back pain ☐

Thank you for your time in completing this questionnaire.
Please now return it immediately in the SAE provided.

PATIENT INFORMATION SHEET

Study Title: The UK Back Pain Subpopulation Study: predictors of outcome in patients receiving chiropractic treatment.

You are being invited to take part in a research study that is being conducted. Before you decide whether to do so, it is important that you understand why the research is being done and what it will involve. Please take time to read this Information Sheet carefully and ask your chiropractor if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The study will involve collecting information on patients receiving chiropractic treatment for low back pain. We would like to monitor your progress before, during and after treatment to enable us to predict which patients respond well to chiropractic care.

Why have I been chosen?

You have been chosen because your chiropractor is one of the 250 chiropractors taking part in the study and is treating the area of your spine (low back) that is specifically applicable to this study.

Do I have to take part in this study?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this Patient Information Sheet to keep and asked to sign a Consent Form. You can still withdraw at anytime and do not have to give a reason. This will not affect the chiropractic treatment you receive.

What will happen to me if I take part?

Throughout the duration of the study you will receive your normal chiropractic treatment. Today you will be asked to complete a questionnaire before you see the chiropractor and also a very brief questionnaire just before you receive your treatment. On one future visit to the chiropractor (at 4th visit or before) you will be asked to complete a brief questionnaire about your progress and finally we will send you a short questionnaire in the post (for you to complete and return in the enclosed SAE) at 3 months and 6 months from the date of your first treatment.

INFORMED CONSENT FORM

Title of Study: The UK Back Pain Subpopulation Study: predictors of outcome in patients receiving chiropractic treatment.

- I confirm I have read and understood the Information Sheet for the above study and have had the opportunity to ask questions.
- I understand that my participation is voluntary, will not affect my treatment in any way and that I am free to withdraw at any time, and without giving a reason.
- I understand that the information collected about me will be kept confidential and treated at all times in an anonymous manner.
- **I AGREE** to take part in the study (please tick box) ☐
  (sign and complete below)

Participant name (please print)……..

Signature……..... Date……

- **I DO NOT AGREE** to take part in the above study (please tick box) ☐

Should you choose to give the following information, this will remain confidential and anonymous.

Age…… Male ☐ Female ☐

Please now hand this back to the receptionist

Appendix 4:

Operations Manual, Step-By-Step Instructions, Flow Chart, letter to chiropractor, letter to clinic reception staff

THE UK BACK PAIN SUBPOPULATION STUDY: PREDICTORS OF OUTCOME IN PATIENTS RECEIVING CHIROPRACTIC TREATMENT

OPERATIONS MANUAL

YOUR CHIROPRACTOR CODE:

……

START DATE FOR YOUR DATA COLLECTION PERIOD:

……

QUESTIONS OR CONCERNS?

Monday – Friday (9am – 4.30pm)

Laura Davies (01202- 436259; email: ldavies@aecc.ac.uk)

EXPLANATION OF THE STUDY

PLEASE TAKE TIME TO READ THE FOLLOWING CAREFULLY.
It should take you no more than 30 minutes to do so.

This study will involve collecting data from low back pain patients receiving chiropractic treatment. The study will enable us to report on predictors of treatment outcome in low back pain patients receiving chiropractic care in the UK and is the largest study of its kind to be attempted in the profession. **Your participation in this study is greatly appreciated and we will be relying on you to strictly follow the protocol outlined in this Operations Manual**. This is of the utmost importance to enable us to collect complete and accurate data. We will then analyse these data and disseminate the results of the study to the profession and publish the findings in the peer-reviewed literature.

- You will be required to collect data from **10 CONSECUTIVE low back pain patients** (new or existing) who agree to participate in the study. It is **vital** that these patients are consecutive otherwise there is the potential for bias which may undermine the study's credibility.

- To be eligible, **patients MUST fulfil ALL of the following:**
  - NEW episode of low back pain (as the main complaint) of any duration, with or without leg pain
  - 18 – 60 years of age
  - NO treatment for low back pain during the past 3 months
  - NOT pregnant
  - literate in English
  - mobile phone user (as text messaging will be used in this study)

- Data will be collected from **you AND participating patients at Visit 1**, and from **participating patients ONLY at Visit 4 (or at an earlier visit if treatment is concluded sooner) using colour-coded questionnaires and forms.**

- The **start date for your data collection period** is shown on the front of this Manual. Data collection continues until completed for all 10 participating patients.

You will find enclosed a **Clinic Manager/Receptionist Information Sheet** for your clinic administrative staff, as it is recognised that their role will be of key importance to the success of the study. A laminated **Step-By-Step Instructions/Flow Chart** about the data collection process is also included for you to refer to.

It is crucial to the success of the study that you adhere to the data collection protocol and if you have **any questions at all about the study at this stage, please contact Laura Davies (telephone: 01202-436259 or email: ldavies@aecc.ac.uk).** It is also possible that you may be contacted to clarify any issues that may arise throughout the data collection period.

DESIGN INFORMATION

Patient Recruitment

Stage 1: on the phone

From the start date of your data collection period (shown on the front of this Manual), **it is *essential* that when patients make an appointment at the clinic they are told:**

- "the clinic is currently taking part in a study about low back pain",
- "you will be given more information about the study when you arrive for your appointment so you can decide if you want to take part or not",
- "there will be no change to your normal chiropractic treatment whether or not you want to take part"
- "we would like you to arrive *10 minutes early* for your appointment to allow time for you to read the information about the study and complete the forms"
- "please *bring your mobile phone* with you"

NB: If the patient is NOT a mobile phone user, they are not eligible for the study

Text messaging (SMS) is a unique feature of this study and it will be used to record short term outcomes directly from patients on a daily basis for 7 days following their first chiropractic treatment. Please ensure your patient has followed the instructions given. Further details about this aspect of the study are provided on the Patient Information Sheet.

Stage 2: at the clinic

When the patient arrives at the clinic for their appointment, EITHER you OR your reception staff will **screen the patient for eligibility for the study** by using the checklist below which is also found on the laminated Step-By-Step Instructions/Flow Chart (please keep this to hand during your data collection period).

To be eligible, patients must fulfil ALL of the following:

- □ **have low back pain (with or without leg pain) as the main complaint**
- □ **be between 18 and 60 years of age**
- □ **have had NO treatment for low back pain in the past 3 months**
- □ **not be pregnant**
- □ **be a mobile phone user**

NB: Although low back pain must be the main complaint,

patients are eligible for inclusion irrespective of any chiropractic

treatment to other area(s) of the spine or body.

HOW TO RECORD DATA

Patient Informed Consent

All patients who are eligible to take part in the study must read the **Patient Information Sheet** and indicate on the **Informed Consent Form** whether or not they are willing to participate in the study. This is expected to take only a few minutes. Patients must also be given the opportunity to ask questions before proceeding.

After reading the Patient Information Sheet:

EITHER: the patient **DOES** verbally agree to take part.
The patient is assigned a **Data Collection Envelope** (by receptionist) and is given TWO copies of the Informed Consent Form to complete and sign. ONE copy of the Informed Consent Form is kept by the patient; the SECOND copy is put in to the Data Collection Envelope. The patient keeps the Patient Information Sheet.

NB: Each patient who agrees to take part in the study and completes the Patient Questionnaire Visit 1 counts as one of the required 10 consecutive low back pain patients, even if they are later found during this consultation to have contraindication(s) to chiropractic care.

OR: the patient **DOES NOT** verbally agree to take part.
The patient completes only ONE copy of the Informed Consent Form. This copy is then put in the **Non-Participant Envelope**.
This patient does NOT count as one of the 10 consecutive patients included in your data collection.

Data Collection Protocol

This section gives details about the data collection documents and how they will be used. The data collection protocol is summarised in the enclosed laminated Step-By-Step Instructions/Flow Chart (please keep this to hand during your data collection period).

DATA COLLECTION ENVELOPE

As above, each patient who agrees to participate in the study will be assigned a **Data Collection Envelope**. The Data Collection Envelope contains all further colour-coded documentation for data collection as follows:

- Patient Questionnaire Visit 1 (*blue)*
- Chiropractor Recording Form Visit 1 (*green)*
- Patient-Practitioner Questionnaire Visit 1 (*yellow*)
- Patient Questionnaire Visit 4 (*pink)*

Throughout the data collection period, please put all completed documentation back into the patient's Data Collection Envelope.

PATIENT QUESTIONNIARE VISIT 1 (*blue*)

The receptionist (if applicable in your clinic) will take the **Patient Questionnaire Visit 1**(*blue*) out of the patient's Data Collection Envelope and hand both the Data Collection Envelope and the questionnaire to the patient. The patient must complete this questionnaire in the clinic reception/waiting area PRIOR to the chiropractic consultation. After completing the questionnaire, the patient sends a text message (instructions given on questionnaire).

CHIROPRACTOR RECORDING FORM VISIT 1 (*green*)

When the patient enters the treatment room, they will hand you the completed Patient Questionnaire Visit 1 (blue) and Data Collection Envelope containing the signed Informed Consent Form (please check this has been signed) and all further documentation for the study.
You will take the **Chiropractor Recording Form Visit 1** (*green*) out of the patient's Data Collection Envelope and complete this form by the end of the patient's consultation today.

- If you find that the patient has any **contraindications** to chiropractic care, the patient **exits from the study at this point** (although they will still count as one of the required 10 consecutive patients). You will complete the relevant parts of the Chiropractor Recording Form Visit 1

(*green*) and put this (with all of the other completed study documentation) in the patient's Data Collection Envelope, complete the checklist on the front of the envelope and seal it. This envelope will be put in the SAE Jiffy Bag (to be returned to the study centre when all 10 patients' data have been collected). <u>This concludes data collection for this patient</u>.

- If there are **no contraindications** to care, the patient will carry on in the study and complete the Patient-Practitioner Questionnaire Visit 1 (see below). You will complete the Chiropractor Recording Form Visit 1 (*green*) by the end of the consultation and put it in the patient's Data Collection Envelope (do NOT seal) and keep this with the patient's file.

<u>PATIENT-PRACTITIONER QUESTIONNIARE VISIT 1 (*yellow*)</u>

This brief questionnaire consists of four statements about the **patient's perception** of how they interacted with you; it is NOT an assessment of your care. The Patient-Practitioner Relationship has been shown to be a robust predictor of treatment outcome in other therapies.

The Patient-Practitioner Questionnaire (*yellow*) must be completed **<u>AFTER examination but BEFORE the patient receives treatment</u>** and will take no more than a couple of minutes. You will take the yellow questionnaire (with accompanying self-seal envelope) out of the patient's Data Collection Envelope, hand it to the patient and allow them some privacy to complete the questionnaire. Once completed, the patient will seal the envelope and return it for you to put back in their Data Collection Envelope.

This concludes the data collection for the patient <u>on the 1st visit</u>. Please keep the Data Collection Envelope and the Patient Questionnaire Visit 4 (pink) visible in the patient's file until the data collection process is finished (by the end of the 4th visit or before if treatment concluded sooner).

<u>PATIENT QUESTIONNAIRE VISIT 4 (OR earlier visit if treatment concluded sooner) (*pink*):</u>

At the patient's 4th visit (at an earlier visit if treatment is concluded sooner), you will take the Data Collection Envelope out of the patient's file and hand the **Patient Questionnaire Visit 4** (*pink*) to the patient to complete (this will take the patient less than 5 minutes). The questionnaire may be completed during or immediately after the patient's appointment with you.

NB: If, for whatever reason, the Patient Questionnaire Visit 4 (*pink*) is NOT completed by the 4th visit, please *DO NOT ALLOW* the patient to complete it at a subsequent visit.

At the same time, you must ALSO give the patient their Data Collection Envelope so they can hand both the completed questionnaire and the envelope to the receptionist (who will put the completed questionnaire in to the envelope).

This concludes ALL data collection for the patient

NB: If there is more than one chiropractor working in your practice, *each chiropractor can participate* by each recruiting 10 patients and each will receive an Operations Manual and set of study documentation.

Return of Study Forms

When data collection for each patient is finished, please ensure the checklist on the front of the Data Collection Envelope has been completed for each patient, seal the Data Collection Envelope and put it into the large **SAE Jiffy bag** provided. Repeat this process until data collection is finished for all patients involved in the study. Finally, seal the large SAE Jiffy bag and return it to the study centre.

PLEASE RETURN THE SEALED SAE JIFFY BAG TO THE STUDY CENTRE AS SOON AS POSSIBLE AND WITHIN ONE WEEK OF THE END OF DATA COLLECTION

DATA PROTECTION

ALL data collected throughout this study will be treated confidentially and anonymously. The data will **ONLY** be made available for research purposes.

ETHICS APPROVAL

This study has been approved by the AECC Ethics Sub-Committee.

SUMMARY

Although the explanation and instructions in this Manual may at first appear to be rather detailed and complex, it has been necessary in order to cover all aspects of the study's design and procedures. Once you start the data collection process, it should become simple and routine with minimal disruption to your practice.

After you have read this Manual, it is recommended that you keep the laminated Step-By-Step Instructions/Flow Chart to hand during your data collection period as this will provide a quick and easy overview of the study.

STEP-BY-STEP INSTRUCTIONS FOR DATA COLLECTION

ON THE PHONE

1. From the start date of your data collection period, patients (new or existing) making an appointment at the clinic must be told:

- "the clinic is currently taking part in a study about low back pain",
- "you will be given more information about the study when you arrive for your appointment so you can decide if you want to take part or not",
- "there will be no change to your normal chiropractic treatment, whether or not you decide to take part"
- "we would like you to arrive *10 minutes early* for your appointment to allow time for you to read the information about the study and complete the forms"
- "please *bring your mobile phone* with you" (NB: if patient is NOT a mobile phone user they are NOT eligible for the study)

IN CLINIC RECEPTION/WAITING AREA

2. Patient **arrives at the clinic** and is screened for eligibility for the study. To be eligible, patients must fulfil ALL of the following:

- ☐ **have low back pain (with or without leg pain) as the main complaint**
- ☐ **be between 18 and 60 years of age**
- ☐ **have had NO treatment for low back pain in the past 3 months**
- ☐ **not be pregnant**
- ☐ **be a mobile phone user (as text messaging will be used in this study)**

3. If eligible, patient reads the Patient Information Sheet.
EITHER: patient **agrees** to take part and is assigned a Data Collection Envelope and signs TWO copies of Informed Consent Form (one copy for patient, second copy put in Data Collection Envelope). Patient keeps the Patient Information Sheet.
OR: patient **does not agree** to take part and completes ONE Informed Consent Form which is put in the Non-Participant Envelope.

4. Patient is given their Data Collection Envelope and the ***blue*** form to complete. Patient sends a text message (instructions given on form).

IN TREATMENT ROOM

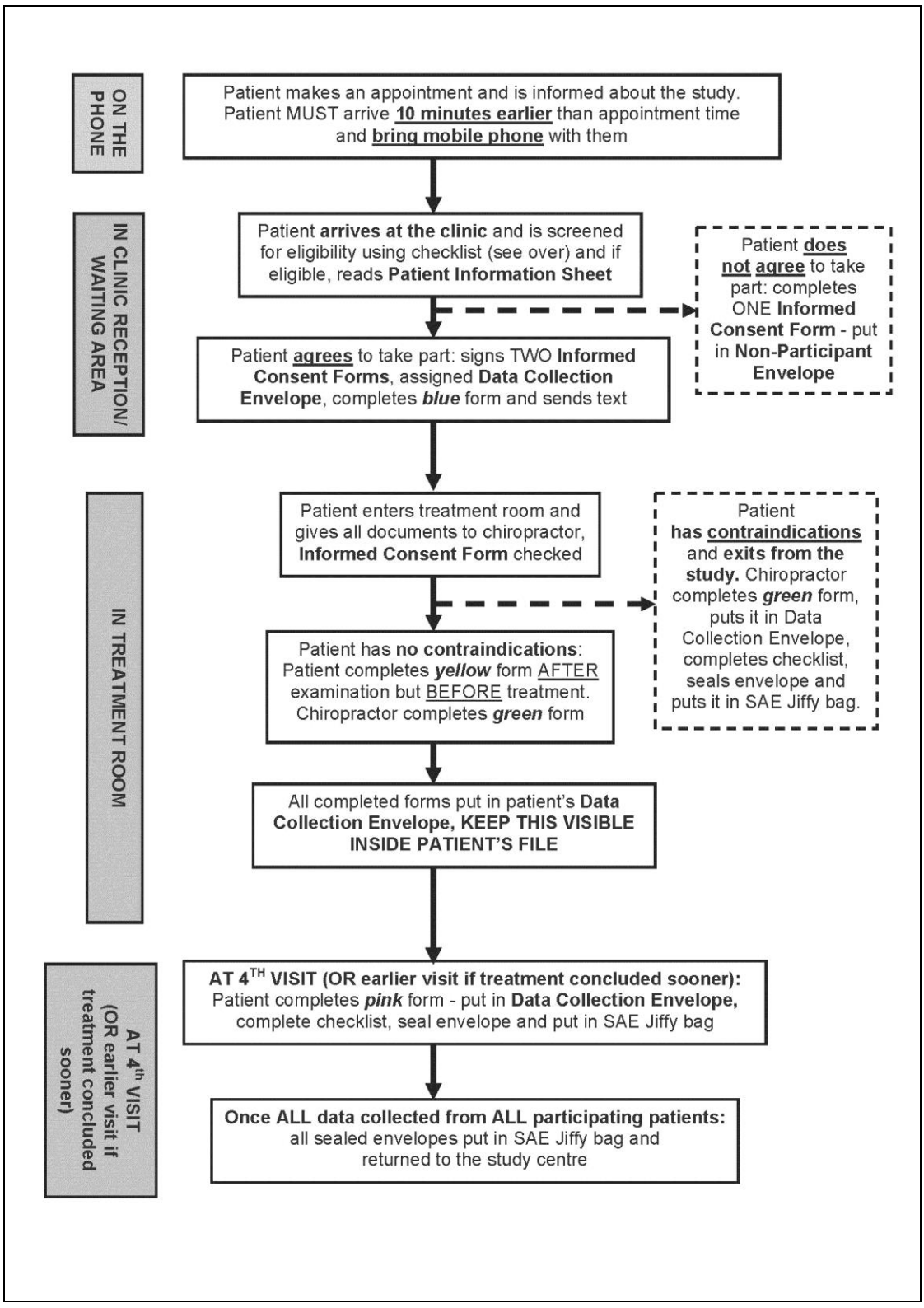
5. Patient enters treatment room and gives ALL documentation to chiropractor. Chiropractor checks Informed Consent Form is signed.
EITHER: patient has **contraindication(s)** to chiropractic care and now exits from the study. Chiropractor completes ***green*** form, puts it in Data Collection Envelope, completes checklist, seals it and puts it in SAE Jiffy bag.
OR: patient has **no contraindication(s)** to chiropractic care and continues in the study. Chiropractor completes ***green*** form and patient completes ***yellow*** form. Completed forms put in Data Collection Envelope but **keep this visible in the patient's file.**

AT 4th VISIT (OR EARLIER)

6. At 4th visit (OR earlier visit if treatment is concluded sooner) patient completes ***pink*** form. Put completed form in Data Collection Envelope, complete checklist on the front of envelope, seal it and put in SAE Jiffy bag.

7. Once ALL data have been collected from ALL participating patients, return SAE Jiffy bag (containing sealed Data Collection Envelopes and Non-Participant Envelope) to the study centre.

SEE FLOW CHART OVERLEAF


ON THE PHONE
Patient makes an appointment and is informed about the study. Patient MUST arrive 10 minutes earlier than appointment time and bring mobile phone with them
IN CLINIC RECEPTION/ WAITING AREA
Patient arrives at the clinic and is screened for eligibility using checklist (see over) and if eligible, reads Patient Information Sheet
Patient does not agree to take part: completes ONE Informed Consent Form - put in Non-Participant Envelope
Patient agrees to take part: signs TWO Informed Consent Forms, assigned Data Collection Envelope, completes blue form and sends text
IN TREATMENT ROOM
Patient enters treatment room and gives all documents to chiropractor, Informed Consent Form checked
Patient has contraindications and exits from the study. Chiropractor completes green form, puts it in Data Collection Envelope, completes checklist, seals envelope and puts it in SAE Jiffy bag.
Patient has no contraindications: Patient completes yellow form AFTER examination but BEFORE treatment. Chiropractor completes green form
All completed forms put in patient's Data Collection Envelope, KEEP THIS VISIBLE INSIDE PATIENT'S FILE
AT 4th VISIT (OR earlier visit if treatment concluded sooner)
AT 4TH VISIT (OR earlier visit if treatment concluded sooner): Patient completes pink form - put in Data Collection Envelope, complete checklist, seal envelope and put in SAE Jiffy bag
Once ALL data collected from ALL participating patients: all sealed envelopes put in SAE Jiffy bag and returned to the study centre

DATA COLLECTION ENVELOPE

Please tick boxes for each COMPLETED form/questionnaire put in this envelope

□ **Patient Questionnaire Visit 1 (*blue*)**

□ **Chiropractor Recording Form Visit 1 (*green*)**

□ **Patient-Practitioner Questionnaire Visit 1 (*yellow*)**

□ **Patient Questionnaire Visit 4 (OR earlier visit if treatment is concluded sooner) (*pink*)**

If Patient Questionnaire Visit 4 (OR earlier visit if treatment is concluded sooner) is NOT COMPLETED, please briefly state the reason why:

…….

YOUR CHIROPRACTOR CODE:

……..

Dear Colleague,

RE: The UK back pain subpopulation study: predictors of outcome in patients receiving chiropractic treatment.

Thank you for agreeing to participate in the above study.

Please find enclosed a copy of the Operations Manual together with the following:

- 1 laminated Step-By-Step Instructions/Flow Chart
- 1 Clinic Manager/Receptionist Information Sheet
- 10 Patient Information Sheets
- 25 Informed Consent Forms
- 10 Data Collection Envelopes each containing the following:
    - Patient Questionnaire Visit 1 (blue)
    - Patient-Practitioner Questionnaire Visit 1 (yellow) (with self-seal envelope)
    - Chiropractor Recording Form Visit 1 (green)
    - Patient Questionnaire Visit 4 (pink)
- 1 Non-Participant Envelope
- 1 large SAE Jiffy Bag

Please now take some time to carefully read the Explanation of the Study that you will find inside the Operations Manual. This should take you no more than 30 minutes. Although the study may appear to be quite detailed, it is crucial that you have an understanding of the procedures we are asking you to follow. If you have any questions at all at this stage, it is essential that you contact Laura Davies as soon as possible either by phone or email using the contact details given on the front of the Operations Manual.

Once you are familiar with the details and understand the procedure, you are ready to start. Please ensure you have checked the front of the Operations Manual for the start date of your individual data collection period. You MUST start data collection on the start date (or as soon as possible thereafter if you miss the start date for any reason).

As you will no doubt understand, it is vital to the success of the study that you explicitly follow the instructions given in the Operations Manual so that the data collected are accurate and complete. The credibility of this study completely relies on your meticulous efforts in this process, and this is enormously appreciated.

Yours faithfully

Laura Davies MChiro DC MCC

Direct line: 01202-436259
Email: ldavies@aecc.ac.uk

LOW BACK PAIN STUDY

Information to Clinic Manager/Receptionist

This study is being conducted by the chiropractic profession to identify factors that predict which low back pain patients will respond well to chiropractic treatment. Many chiropractors in the UK are being asked to participate and the chiropractor(s) in the practice where you work has (have) agreed to participate in the study.

There are several steps to the study in order to collect all the data we need from the patients and chiropractors participating in the study. The chiropractor will explain to you how you will be involved in this process to ensure that the data are collected efficiently and effectively with minimal disruption to the clinic. It is absolutely crucial to the success of this study that the data collected are complete and accurate. Please ask the chiropractor if you are unsure about any part of the process.

Your help with this study is greatly appreciated. It is well recognised from previous studies carried out in chiropractic practices that the clinic administrative staff are of key importance in ensuring the success of these studies.

Thank you for your participation in this study.

Laura Davies MChiro DC MCC
Study Investigator

Appendix 5: Text-messaging - questions and messages

Introductory text message (sent directly after the patient enrolled in the SMS study):

"Welcome to the study. From tomorrow, for the next 7 days, please reply to each text about your back pain. Thank you."

Text message questions sent to participating patients from Day 1 to Day 7 following the 1st visit:

Question 1:

"Over the past 24 hours, on average, how would you rate your low back pain on a scale where 0 is 'no pain' and 10 is 'worst pain possible'?"

Question 2:

"Over the past 24 hours, has your low back complaint changed? 1=much worse, 2=worse, 3=no change, 4=better, 5=much better."

Text message of thanks (sent directly after final SMS response was received):

"Thank you for your participation."

Text message questionnaire reminders at 3 months:

Sent after 10-14 days if postal the questionnaire was not received:
"Hello, please complete & return the low back pain questionnaire you've recently received in the post. Your help is vital to the success of the study. Thank you."

Pre-emptive message sent on the day of posting the questionnaire:
"Hello, please complete & return the back pain form you'll soon receive in the post. Thank you, your help is vital to the success of the chiropractic study."

Appendix 6: Letter of ethics approval from the AECC Ethics Sub-Committee

AECC

ANGLO-EUROPEAN COLLEGE OF CHIROPRACTIC
Education for a Major Health Care Profession

28 August 2008

Dr Laura Davies
AECC
Bournemouth

Dear Laura

Re: The UK Back Pain Subpopulation Study: predictors of outcome in patients receiving chiropractic treatment

Thank you for your letter dated 21 August 2008. I am now satisfied that this application meets ethical requirements, and as such is approved.

May I take this opportunity to wish you every success in the study.

Yours sincerely

Professor J E Bolton, PhD MAEd FHEA FCC(Hon)
Chair, Research Ethics Sub-Committee

c.c. Dr D Newell

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V.A.T. No: 896 1199 74 Limited by guarantee Registered Office as above Registered in England No. 653 859 Charity registered No. 306 289